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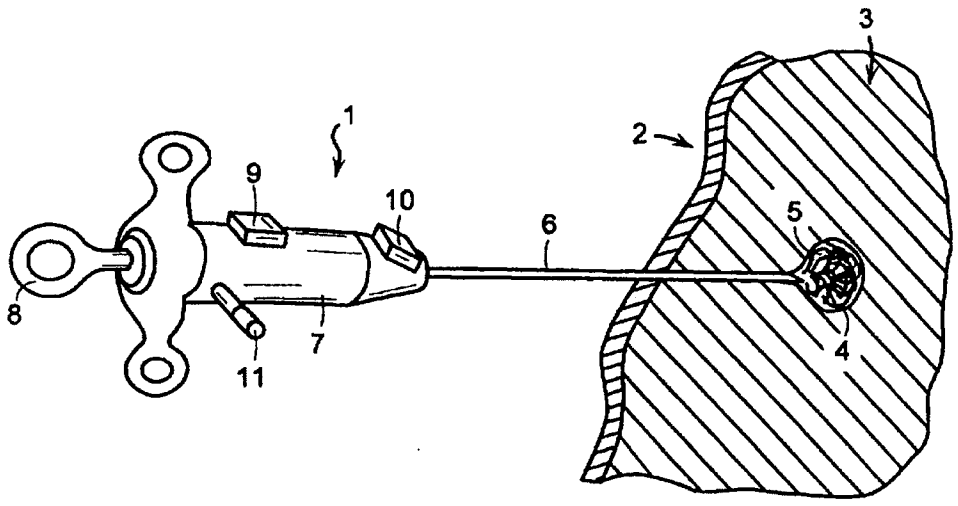

(57) Abstract

A method of introducing continuous lengths of filament into the body in surgical procedures in which it is desirable to place a significant amount of material into the body through a small portal. The material so introduced may serve to bulk a tissue of cavity of the body or to occlude a vas, as well as to introduce diagnostic or therapeutic agents into a site in the body. A device for implementing the method has a mechanism for feeding the filament through a conduit in such a manner that sufficient force is applided to the filament that it is forced into the desired site. In one embodiment, a system of reciprocating cannulae and synchronized grippers is used to supply the requisite force to the filament.

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Device, System and Method for Implantation of Filaments and Particles in the Body

Technical Field

The present invention relates to a device and method for therapeutic insertion of suture and other materials into body tissue in filamentous and particulate form.

Background Art

Increasingly in medicine and surgery, the need arises to place a mass of material either into body tissue or into a space in the body proximate to body tissue for various clinical purposes. These purposes include the bulking of tissue as a therapy for intrinsic sphincteric deficiency (ISD) which gives rise to incontinence. In some types of incontinence, a decrease in urethral resistance leads to urinary leakage during stress. This leakage is embarrassing, and may cause the person to change their life-style to avoid activity. Recently, various injectable materials have been suggested for the purpose of 'bulking' the peri-urethral space, coapting the urethra, and thus increasing the urethral resistance.

Other clinical applications include the implantation of material include the occlusion of aneurysms, arteriovenous malformations (AVMs), and fistulas, as well as the occlusion of the blood supply to tumors, especially cranial tumors, prior to surgery to reduce bleeding during surgery.

To insure that such procedures are minimally invasive, it was clinically determined that bulking, for example, should be accomplished through needle injection. Due to the use of a needle, it was believed that it was necessary to reduce the material to a liquid suspension or particulate so that it might be capable of being passed through a needle into the tissue. This reduced the number of candidate materials significantly. Teflon (PTFE) particles, silicone particles, collagen suspensions, and various other materials were tried. Most of the problems associated with the therapy were associated with the material. For example, collagen resorbed too quickly, creating the need for many repeat therapies. Teflon particles migrate through the body and are thus clinically undesirable.

Known technology has similarly limited the materials which can be delivered transvascularly, endoscopically, or via a conduit in conjunction with a laparoscope. Articles that are delivered by pushing and utilization of these devices are limited, typically, either to

fluids or to relatively stiff solids.

The controlled release of drugs from polymer and from surgical suture is another therapeutic modality known in the art. Application of this technique, however, has hitherto required the insertion of suture using conventional methods of *pulling* the suture into the tissue, as by means of a sewing needle or tweezers, raising difficulties of access to the site of implantation.

Summary of the Invention

The present invention expands the domain of materials that may be used for bulking as well as for other cellular and drug delivery applications. The invention allows for a filament, as defined below, to be introduced through a needle or other conduit, allowing such well-known biocompatible materials as those used in suture to be considered. With this novel advance, not only can the material have a bulking effect, but depending on the other properties of the filament used, it may add other mechanical attributes such as springiness, rigidity, flexibility, mass, orientation, and permeability. Further, the material being introduced may be a solid, compressed particulate or composite, thereby opening up a range of possible functions the material may perform such as drug delivery, radiation, chemotherapy or thermotherapy. The three- dimensional nature of the end result may be very appropriate to provide a scaffolding for cellular ingrowth for cells either injected with the filament, or those induced to grow into the matrix.

The device is capable of placing a significant amount of material in the body through a small portal, i.e., an opening in the body as defined below. This material may preloaded with a drug, or cells, or some other active material to produce some desired effect with the body. The dosage may be controlled by the length of the filament and the nature of the preloading, and may be modified at the time of delivery to the length of choice. Such a method may be useful for the delivery of subcutaneous heparin, insulin, contraceptive substances, and other pharmaceuticals useful for heart disease, smoking cessation, etc. The advantage of this approach over other subcutaneous drug delivery devices is its extremely low profile, and the ease in which it is positioned within any site in the body, in particular, in the proximity of the tissue to be affected.

In accordance with a preferred embodiment of the invention, a method is provided for modifying a tissue property of a subject, wherein the method consists of providing a quantity

of filament, opening a portal in the body of the subject, where both "filament" and "portal" are defined below, inserting the filament through the portal into a region in the vicinity of the tissue, and localizing the filament in the region so as to modify the tissue property. The tissue property to be modified may include the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue. The filament is inserted directly, or with the aid of an endoscope or a laparoscope. Embodiments of the invention provide methods for bulking the tissue of a subject, coapting the walls of a vas, where "vas" is defined below, occluding a vas, preventing pregnancy, sterilizing a subject, clotting an ulcer, treating an aortic aneurism, treating a bleeding esophageal varix, providing chemotherapy, releasing a drug, catalyzing biochemical reactions, providing birth control, supporting cell growth in a subject, sewing body tissue, delivering anesthesia, and delivering a stent into a vas. Each of the aforesaid methods has the steps of providing a quantity of filament and inserting it into the body. The filament may be preloaded as described above. In further embodiments of the invention, a continuous length of filament may be severed to provide a desired length of filament within the body of the subject, and fluid may also be injected into the subject in conjunction with the filament. Additionally, in accordance with an alternate embodiment of the invention, suture is provided in particulate form, suspended in a liquid carrier to create a suture suspension, and inserted through a portal in the body of a subject to modify a tissue property that includes at least one of the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue.

In another embodiment of the invention, a method is provided for removing filament from a site in the body that consists of the steps of inserting a hollow shaft into the site, hooking the filament with a hooked tool, and withdrawing the filament via the hollow shaft.

In accordance with another aspect of the invention, a device is provided that has a conduit for insertion into a designated site in the body, and a feeding mechanism for supplying filament along the axis of the conduit in a manner such that support is provided across all lengths of the filament longer than three times the diameter of the filament. The conduit may be rigid, as well as semi-rigid or flexible.

In one embodiment of the invention, the feeding mechanism has an inner cannula with an inner diameter corresponding generally to the diameter of the filament and a mounting arrangement, which may be a coaxial outer cannula, for permitting the axial movement of the inner cannula. Finally, an actuator mechanism is provided for urging the inner cannula in

axial reciprocation consisting of forward motion and retrograde motion with respect to the mounting arrangement. In alternate embodiments, the actuator mechanism may have a combination of grippers or a gripper and a brake. Additionally, the inner cannula may have distinct proximal and distal segments and a containment spring for retracting the distal segment toward the proximal segment during retrograde motion of the distal segment.

In further embodiments of the present invention, a tip may be provided on the mounting arrangement for penetrating body tissue, and a window may be provided proximally to the tip to allow filament to be fed into the site. Filament cutters are provided in several alternate embodiments to allow desired lengths of filament to be left in the body. In one filament cutter embodiment, a torquable head is disposed adjacent to the distal end of the conduit with a shearing surface disposed on at least one of the torquable head and the distal end of the conduit such that rotation of the torquable head severs the filament. In another filament cutter embodiment, a shearing surface is provided on at least one of the inner cannula and mounting arrangement of the device such that relative motion of the inner cannula and mounting arrangement cause shearing of the filament.

Other filament feeding mechanisms are provided in alternate embodiments of the invention which include conveyor belts engaged against the filament, a toothed wheel and idler wheel for advancing the filament, and a reciprocating shaft which drives the filament forward in the shaft and then springs back in disengagement from the filament. A motor may be employed for repetitively cycling the feeding mechanism.

In accordance with another aspect of the present invention, a device is provided for removing a filament from a site in the body where the device consists of a conduit and a hook for snagging and withdrawing the filament through the conduit.

In accordance with yet another aspect of the present invention, a stent is provided for modifying a tissue property of a subject where the stent consists of at least one strand of filament, and where the tissue property so modified may include at least one of the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue.

Brief Description of the Drawings

Fig. 1 is a schematic illustration of a filament injection device 1 in accordance with a preferred embodiment of the present invention.

Fig. 2 illustrates the principal components of a filament injection device in

accordance with a preferred embodiment of the present invention.

Figs. 3A-3C show cross-sectional views of a filament feeding mechanism in the advancement stage of a filament feeding cycle in accordance with the embodiment of the invention shown in Fig. 2.

Figs. 4A and 4B show cross-sectional views of a filament feeding mechanism in a the reset stage of a filament feeding cycle in accordance with the embodiment of the invention shown in Fig. 2.

Fig. 5 shows an exploded view of a filament feeding mechanism according to an embodiment of the invention.

Fig. 6 is a cross-sectional view of the distal tip of a filament feeding mechanism in accordance with an embodiment of the invention.

Figs. 7A and 7B are cross-sectional views of the distal tip of Fig. 6, showing a filament cutting mechanism according to an embodiment of the invention.

Fig. 7C is a perspective view of the distal tip of a conduit in accordance with an embodiment of the invention showing an alternate filament cutting mechanism.

Fig. 7D is a cross-sectional view of the filament cutting mechanism of Fig. 7C.

Fig. 8 is a cross-sectional view of an filament feeding mechanism according to an alternate embodiment of the invention.

Fig. 9 is a schematic of a powered drive system for cycling the shaft 27 with the touch of a button.

Fig. 10 illustrates a layout of an alternative embodiment of the system.

Fig. 11A is a cross section of the result after the device has been used to coapt the walls of a tubular structure within the body.

Fig. 11B illustrates an embodiment of the invention for treatment of an ulcer.

Fig. 12 illustrates an embodiment of the invention for removing a filament in the body after it has been placed.

Figs. 13A-13C illustrate use of the device of Fig. 1 for passing suture through and around tissue, and, in Fig.13C, for creating a series of linked loops.

Fig. 14 illustrates the mechanism through which particle may be injected into the body in accordance with another embodiment of the invention.

Figs. 15A and 15B show respectively a descended bladder of a female subject and the same bladder after it has been elevated by use of a filament implanted in accordance with an

embodiment of the invention;

Fig. 16 shows an embolism that has been achieved in a blood vessel by means of a filament implanted in accordance with an embodiment of the invention;

Fig. 17 shows an aneurysm that has been filled by means of a filament implanted in accordance with an embodiment of the invention.

Figs. 18 through 26 illustrate various embodiments of the invention for achieving the movement of a filament along a desired path so as to permit implantation of the filament;

Figs. 18A and 18B illustrate an embodiment for achieving movement of a filament utilizing a pair of conveyor belts symmetrically engaged against the filament;

Fig. 19 illustrates an embodiment for achieving movement of a filament utilizing a toothed drive wheel against which the filament is engaged by an idler wheel;

Fig. 20 illustrates an embodiment, similar to that of Fig. 19, utilizing a toothed drive wheel against which the filament is engaged by an idler wheel, but wherein the filament is also engaged against the drive wheel by a guide having an arcuate surface that general conforms to the radius of the drive wheel;

Figs. 21A and 21B illustrate and embodiment, similar to that of Fig. 19, utilizing a toothed drive wheel against which the filament is engaged by an idler wheel, but wherein the idler wheel is soft;

Fig. 22 illustrates an embodiment for achieving movement of a filament utilizing a toothed drive wheel against which the filament is engaged by a tubular guide;

Figs. 23A and 23B illustrate an embodiment for achieving movement of a filament utilizing a drive wheel against which the filament is engaged by an idler belt;

Figs. 24A through 24E illustrate an embodiment for achieving movement of a filament utilizing a pair of axially reciprocating tubular members, within which the filament is disposed, in conjunction with a periodically clamping finger;

Figs. 25A through 25E illustrate an embodiment similar to that of Figs. 24A through 24E but in which the coil springs of the latter figures are supplanted by complementary mating extensions of the tubular members;

Figs. 26A and 26B illustrate an embodiment for achieving movement of a filament utilizing a pair of arms that are caused to reciprocate axially while being alternately opened and closed at the opposite ends of each stroke;

Figs. 27A through 31D illustrate embodiments of the invention in which a region

proximate to a tip of a cannula carrying a filament is provided with an arrangement, for cutting the filament, utilizing a concentrically disposed member and a window in both members through which the filament is placed and severed;

Figs. 27A and 27B illustrate an embodiment wherein the outer member is pulled proximally with respect to the inner member to achieve cutting;

Figs. 28A and 28B illustrate an embodiment wherein the outer member is pushed distally with respect to the inner member to achieve cutting;

Figs. 29A through 29C illustrate an embodiment wherein the inner and outer members are rotated with respect to one another to achieve cutting;

Figs. 30A through 30D illustrate the way a tip, having a cutting arrangement of one of the types described above, may be employed in conjunction with a suitable window to prevent the presentation of undue pressure, by the distal end of the filament, on tissue of the subject on whom the invention may be used; and

Figs. 31A and 31B, and 32A and 32B, illustrate a possible configuration for a case for an embodiment similar to that of Figs. 26A and 26B.

Detailed Description of Specific Embodiments

In order to provide an overall understanding of the present invention, the method, system, and device of the invention will be discussed with reference to the application of the invention to provide tissue bulking. However, it will be understood by persons of ordinary skill in the art that the general method, system, and device, described herein, are equally applicable to all cases in which filament injection would have value. A list of possible uses for the technology includes, but is not limited to, the injection of a filament-based system of drug delivery into tissue, the subcutaneous or interstitial injection of a filament for the purpose of bulking, shaping, applying pressure, or adding other mechanical properties (such as springiness or rigidity), and the injection of a filament to act as a matrix or lattice in which a cellular process may proceed (i.e. bone replacement, healing, implanted cellular scaffolding).

Other clinical uses include the injection into the body of a filament bearing other properties such as radiopacity, magnetism, radioactivity - radiation, or fluorescence, all suited for application as a clinical tracer or therapeutic agent. Similarly, the filament may have chemical properties which allow it to serve as a tracer of specified biochemical processes or

as a catalyst to stimulate or enhance desired reactions within the tissue. This invention represents a new concept in the delivery and retrieval of mass as well as of therapeutic and diagnostic agents.

The applications of tissue bulking alone are manifold, once it is appreciated that tissue bulking may be achieved conveniently and at low risk using the method, system, and device of the present invention. Tissue bulking applications include, but are not limited to periurethral bulking of the urinary sphincter, support of the urethra, therapy of vesicourethral reflux, prevention of esophagal reflux via the gastroesophageal sphincter, and treatment of the anal sphincter for treatment of fecal incontinence. Other applications of tissue bulking which may be achieved using the present invention include the bulking of blood vessels, both internally or externally, in association with the treatment of bleeding ulcers. The applications listed are given by way of example, though it is to be understood that the scope of the invention is not limited to the applications listed but includes all applications wherein filamentous material is usefully injected into the body.

As used in this specification and in the claims hereto appended, a material, provided in a threadlike form, will be referred to as "flaccid" if its buckling stress, measured in units of force per unit cross-sectional area of the material, is less than or comparable to the shear strength that is typical of soft body tissue (such as the dermis). Shear strength is expressed in the same units as stress. Buckling stress, as is known in the mechanical arts, refers to the force per unit area applied axially to a member which causes deformation of the member in a direction orthogonal to the axis of the member. It is also known in the mechanical arts that the buckling stress of a member is proportional to the off-diagonal compressive modulus, (i.e., the ratio of axial compressive stress to the strain induced transverse to the axial direction) and inversely proportional to the square of the ratio of unsupported length to diameter of the member. Thus, the longer or finer a thread is, the less force per unit area is required to cause it to buckle.

Clearly, it is known that rigid, needle-shaped implements, such as all manner of needles or staples, may be driven into tissue upon application of sufficient axial force along the direction of insertion. By way of contrast, the present invention teaches a method of inserting materials which are flaccid rather than rigid. In view of the definition of "flaccid" provided above, flaccid materials are inherently incapable of being driven into tissue by the application of axial force. These materials are referred to, collectively, as "filament." More

particularly, as used in this specification and in the claims hereto appended, the term "filament" refers to a flaccid material, and may include biocompatible materials such as polypropylene, Nylon, DACRON™, polybutylester, polybutylethylene, polyglycolic acid (PGA), and variations thereof, and any other material, naturally occurring, biological, or man-made, which has been chosen for a particular application on the basis of biocompatibility, biodegradability, or any other desirable property. Other filament materials useful in particular clinical applications are composite, woven, or solid, and include silk, metal, 'gut', collagen, elastin, cartilage and bone. The term "filament" encompasses, particularly, all materials, such as polypropylene, currently supplied and used as suture material and referred to thereas. Additionally, the term "filament" encompasses the use of materials having shape memory, such as nitinol, which may be used to particular clinical advantage. Whereas many of the foregoing materials may be formed into a wire-shaped member that is not flaccid as defined herein, the term "filament" in this description and the accompanying claims is limited to the embodiment of such materials in their flaccid forms.

Since the "filament" is flaccid, it will be appreciated that materials of this category, if pressed, unguided, against the surface of body tissue, are likely to buckle rather than to cleave the surface, penetrate into the body tissue, or expand or dissect a space into the tissue.

When a filament is bent, such as under its own weight or due to compressive buckling, the inner regions yield under compression. Force applied to the distal end of a bent filament by driving it against a surface is no longer truly axial and has a vector component which leads to further bending. Plastic deformation may inhibit the return of the filament to the original configuration even after removal of the load. However, the filament need not undergo any plastic deformation if it is suitably introduced and trapped within the body tissue, in accordance with the present invention.

In the prior art, suture is treated as a flaccid material in that it is pulled through tissue, as by a needle or tweezers, rather than pushed. For suture or other filament sufficiently fine, large forces per unit cross-sectional area can be developed, using the teachings of the present patent, over small cross sectional areas. The force per unit area applied by the tip of the filament can readily exceed the shear strength of the body tissue so that the filament can thereby cleave and penetrate the tissue. The recognition of this ability of a filament, using the methods of this invention, to penetrate body tissue, enables the host of clinical applications which are described herein.

As used in this description and in the appended claims, a "portal" for insertion of filament into the body refers to any naturally existing or created opening into the body or a tissue. The invention teaches the insertion of filament into the vicinity of a tissue, where, as used in this description and in the appended claims, a "vicinity" includes at least a portion of the tissue itself, as well as its walls, and proximate tissue or body cavity. Since some tissues may be too small, fragile, or sensitive to permit direct insertion of filament, filament may be inserted, in accordance with the teachings of the present invention, into proximate tissue that is near but not directly associated with the target tissue.

Additionally, insertion of filament may be achieved via a vas, where, as used in this description and in the appended claims, the term "vas" refers to any duct, vessel, passageway or cavity occurring in the body, either by natural anatomical formation or through surgical intervention.

Fig. 1 illustrates a filament injection device **1** in accordance with a preferred embodiment of the present invention. Here a needle **6** is inserted through the skin **2** into the body **3**. A small filament **5** is injected into an interstitial space **4**. The needle **6** is attached to a housing **7** which has an inlet **11** for fluid, a fluid control **8** for fluid injection, an injection control **9** to advance the filament, and a cut control **10**. Those skilled in the art will recognize that needle **6** may also be a rigid, flexible, deformable, malleable, semi-rigid or semi-flexible cannula or catheter inserted percutaneously, endoscopically or transvascularly. Further, filament **5** may also be a resorbable or non-resorbable suture, wire, or any of the other materials comprised within the definition of "filament" given above. This filament may be a composite material embedded with drugs, cells, or radioactive substances. The combination of drugs with polymer to provide programmed release of the drugs within the body is known, as described in A. Loh, Controlled Release of Drugs from Surgical Suture, 1987, which is herein incorporated by reference. The insertion into the body of a filament which has been preloaded with a therapeutic or diagnostic agent, whether by techniques of embedding or impregnating within the filament material or otherwise bonding to the filament, whether at the time of manufacture or at the time of insertion into the body, is included within the scope of the invention. While no other working channels are shown in the device, those skilled in the art will recognize that the modification of the device to permit additional instrumentation to be passed within or along-side the device does not depart from the invention. Such other channels may be provided for introducing energy guides, wires, endoscopic visualization

devices or surgical tools. The device as shown would be easily advanced into the periurethral space for tissue bulking or drug delivery to treat incontinence, or the perivascular space for venous reconstitution or drug delivery, or the interstitial space within a tumor for chemotherapy, radiation or magnetic thermal therapy.

In this specification and in the appended claims, the term "distal" denotes the end of the filament injection device **1**, or the end of any of the component parts of filament injection device **1** such as conduit **6**, which is located toward the point of delivery of filament **5** into the body **3**. Conduit **6** serves as the delivery cannula through which filament **5** is introduced into the body of the subject. Similarly, in this specification and in the appended claims, the term "proximal" denotes the end of the filament injection device **1** or the end of any of the component parts of filament injection device **1** which is located away from the point of delivery of filament **5** into the body **3**. Because of the need to minimize the diameter of distal end **12** of filament injection device **1**, in order to avoid leaving a large hole in the body **3** of the subject, the bulkier suture feeding mechanism typically resides in the bulkier proximal section **7** of the device. Therefore, the feeding mechanism, described below, cannot pull on the filament but must push it forward. In order to allow for pushing a flaccid material into the body, the zone between feeding mechanism **7** and conduit **6** over which filament **5** is unsupported must be kept to a minimum. In some preferred embodiments of the invention, there is no unsupported length of filament **5**, while, in other embodiments, a length of filament **5** is unsupported, and is, typically, no larger than three times the characteristic diameter of the filament. Additionally, it will be appreciated that an interstitial stent, formed of either a single unitary strand of filament or multiple strands, may be employed generally, within the framework of the teachings of the invention, for modifying any property or properties of an organ or tissue by introduction into the vicinity of the organ or tissue as described herein.

Referring now to FIG. 2, wherein the principal components of a filament feeding device used, in accordance with a preferred embodiment of the invention, to advance the filament into the tissue. Inner cannula **14** is a tubular section having a diameter closely matched to the diameter of filament **5** for which inner cannula **5** provides support. Inner cannula **14** prevents filament **5** from buckling or jamming as a result of the axial force pushing it into the body, and is, in turn, retained axially within a coaxial outer cannula **15**. In alternate embodiments, inner cannula **14** may be retained by other manner of mounting

arrangements, to include channels, as is well known to a person of ordinary skill in the art.

FIG. 3A shows a cutout window **16** in the proximal section of inner cannula **14**. Cutout window **16** exposes a small section of filament **5** and allows actuating pad **17** to couple filament **5** and inner cannula **14** to an actuator mechanism **502** (shown in FIG. 5). Actuating pad **17** is referred to, functionally, as a "gripper." FIG. 3B shows actuating pad **17** depressed in a direction **18** transverse to filament **5** in order to engage it securely. FIG. 3C shows the advancement, by means of the action of actuator mechanism **502** (shown in FIG.5), of actuating pad **17** to the left, and the advancement, along with actuating pad **17**, of both inner cannula **14** and filament **5** such that a length of filament **5** equal to the distance **19** of motion of actuating pad **17** is urged into the body tissue.

Figs. 4A and 4B illustrate the next step of the filament feeding action, the reset part of the cycle, wherein actuating pad **17** is retracted from contact with filament **5** and is urged proximally, in retrograde direction **404**, such that inner cannula **14** and actuating pad **17** return to their original proximal position. In a preferred embodiment of the invention, inner cannula **14** has a distal segment **408** and a proximal segment **410**, separated by containment spring **412**. The direction **406** of retraction of the distal segment **408** of inner cannula **14** is referred to as the retrograde direction. During the reset part of the filament feeding cycle, the filament **5** itself is prevented from coming back out of the body tissue by means of friction brake **402**, located proximally to actuating pad **17** , which secures filament **5** within the proximal segment **410** of inner cannula **14**. Retraction of distal segment **408** of inner cannula **14** is achieved, in a preferred embodiment of the invention, by means of the force supplied by containment spring **412** in compression. The feeding action described allows a high force per unit cross-sectional area to be applied in advancing filament **5** into the body tissue while a lower force is supplied by containment spring **412** to retract the distal segment **408** of inner cannula **14**.

Referring now to Fig. 5 wherein the components of a filament feeding mechanism, designated generally by numeral **500**, are shown in exploded view. Actuator mechanism **502** is shown to comprise a thumb pad **504** which the physician uses to advance slider **506** forward to a stop in the slider guide **508**. By pressing on distal part **505** of thumb pad **504**, the physician causes activator pad **17** (shown in Figs. 4A and 4B) to come into contact with filament **5** (shown in Fig. 4A), and, as he also urges thumb pad **504** forward, he feeds a discrete amount of filament **5**, paid off of spool **510** along feed axis **512**, into the body tissue,

according to the mechanical principle described above with reference to Fig. 3. In an alternate embodiment, the actuation of filament advancement is accomplished by means of an electrical stepper, using mechanical principles known to persons having ordinary skill in the art. The amount of filament fed in each advancement step of the feeding cycle is, typically, on the order of 5 mm. However, design and adjustment of filament feeding mechanism **500** can provide for a longer or shorter length of filament to be fed in each advancement step, indeed, any desired length of filament may be provided per advancement step. To reset the mechanism for the next feeding, the physician depresses the proximal part **503** of thumb pad **504**, thereby freeing pawl **514** from a ratchet rack **522** contained in a body **524**, and allowing thumb pad **505** and distal segment **408** of internal cannula **14** (shown in Fig. 4B) to retract, according to the principle discussed above with reference to Figs. 4A-4B. Since the actuating pad **17** is now held up away from the filament **5** and since the suture is held in its forward position by brake **402**, the length of filament previously fed remains in the body tissue.

Fig. 6 shows a cross sectional view of the distal tip of a filament feed mechanism, according to a preferred embodiment of the invention. It has been found that if the tip **600** of the filament **5** itself is allowed to push straight into the body tissue at the start of the procedure, it can occasionally penetrate the tissue and travel further ahead than clinically indicated, and, instead of remaining in the area surrounding tip **602** of outer cannula **15** and creating the intended localization of filament for purposes of tissue bulking, vas occlusion, or any of the other clinical purposes of filament localization. A solution to this problem, according to a preferred embodiment of the invention, is to provide cutout window **604** in outer cannula **15**, immediately proximally to tip **602**. As the filament is urged forward, according to the feeding method described above, or otherwise, it bends and then buckles toward the only opening in the area: window **604**. Thus the filament enters the body tissue in a gentle sideways manner, presenting to the tissue an area large enough that the force per unit area is insufficient to shear the tissue and to cause inadvertent penetration. Once a filament coiling process is started in this manner, the implanted filament remains within the target region of the body. In order to point the outer cannula window **604** in the direction in which the filament is to be applied to the tissue, the outer cannula **15** is fully rotable about its axis in fixed increments, typically 45-degree increments. A ball plunger arrangement holds the outer cannula in the chosen orientation, according to mechanical principles known to a person of ordinary skill in the art.

When sufficient filament has been introduced into the body to achieve the requisite tissue bulking or other clinical objective, the physician cuts the filament before withdrawing the device. Thus, in accordance with the present invention, the filament stored in the filament injection device is longer than the amount of filament which is intended to be used in the application at hand. Thus, the desired length may be determined during the course of the procedure and severed after it is deployed into the body of the subject. One method of cutting the filament is described with reference to Figs. 7A and 7B. In a preferred embodiment of the invention, stop **702** is provided within lumen **704** of outer cannula **16**. Distal end **706** of distal segment **412** of inner cannula **14** is provided with a sharpened edge. Thus, when sufficient filament **5** has been injected to constitute the clinically indicated implant **700**, distal segment **412** of inner cannula **14** is thrust against stop **702**, cutting off filament **5**. To allow the inner cannula **14** to advance as far as the cutting stop **702**, a trigger **518** (shown in Fig. 5) must be activated by the physician, releasing slider stop **520** (shown in Fig. 5) which, otherwise, prevents the advance of inner cannula **14** to the point of cutting off the filament. In an alternate but equivalent embodiment, the sharpened edge is provided within lumen **704** of outer cannula **16**, while, mutatis mutandis, the cutting stop is now provided at the distal edge of inner cannula **14**. The cutting action for cutting off the filament remains as described. In an alternate embodiment, the cutting function is achieved by providing a high-tolerance fit of the inner cannula **14** so that when the distal edge **706** of the inner cannula **14** is pushed past distal edge **606** (shown in Fig. 6) of window **604** (shown in Fig. 6), filament **5** is sheared. Shearing of filament **5** may also be achieved, alternatively, through rotation of inner cannula **14** with respect to outer cannula, where shearing surfaces are provided on one or both members, as would be apparent to a person skilled in the art.

Another method of cutting the filament is described with reference to Figs. 7C and 7D. In an alternate embodiment of the invention shown in Fig. 7C, conduit **708**, which can be used in conjunction with any of the filament feeding mechanisms described herein, is provided, at its distal end, with a torquable head **710** containing window **712** within distal surface **714**. Referring now to the cross sectional view shown in Fig. 7D, torque is transmitted to rotate torquable head **710** via torque wire **716** which runs through conduit **708** so that torque may be applied at its proximal end (not shown). When torquable head **710** is rotated, filament **5** is cut by blade inset **718**, such that, upon withdrawal of conduit **708** from the body, the requisite length of filament **5** is left in the body. In one embodiment of the invention, a

cannula **720** is provided through conduit **708**, parallel to filament **5**, so that fluid or a guide wire may be introduce via cannula **720** through port **714** in torquable head **710** into the body region into which filament **5** is being inserted.

Fig. 8 shows the detail of how the filament may be advanced into the tissue. Within the lumen **26** at the tip of needle **6**, the filament is held in a position against the wall by struts **24** and **25**. Shaft **27** has a head **21** and a channel **22** spaced back from the tip of head **21** a small distance. As shaft **27** is advanced, head **21** comes in contract with partial pivot **23** and is forced downward, engaging filament **5**. As shaft **27** continues to advance, filament **5** is pushed forward as head **21** subluxes under pivot **23**. With the continued advancement of shaft **27**, eventually channel **22** aligns with pivot **23**, permitting it to spring back into its original shape, disengaging filament **5**. Then, as shaft **27** is withdrawn, head **21** rides over pivot **23**, losing contact with filament **5** preventing inadvertent withdrawal of filament **5**. Finally the cycle is complete when head **21** pops over pivot **23** and snaps back into its original shape and position at the start of the cycle.

Fig. 9 illustrates a schematic of a powered drive system for cycling the shaft **27** with the touch of a button. When switch **38** is turned on, power to a small motor **35** turns a set of gears **33** and **34** which drive a bar linkage **32** riding in a channel **31**. The bar linkage **32** is attached to the shaft **27** at the point within or near the channel **31**. Power source **37** may be connected to processor **36** which may be capable of correlating, tracking or controlling 'on-time' as it relates to the mass of filament deposited within the body. Alternatively, those skilled in the art will recognize that various mechanical methods are easily applied which would allow the shaft to be man-powered or mechanically driven.

Fig. 10 illustrates a layout of an embodiment of the system. Fluid control **8** may drive fluid stored in vessel **43** forward through the tip of needle **6**. A principal purpose of the fluid is to dilate the space to be occupied by the filament; in this connection, the fluid may be a suitable liquid such as saline, although the fluid may also or alternatively include anesthetic, antibiotic, or other medication. Other methods may also be used for dilation of the space, including inflation of a temporary balloon. Alternatively, the implantation of the filament itself may be used to cause dilation of the space. Further, it is envisioned that an endoscope may desirably be inserted into the space before, during or after the treatment to ensure proper placement. Injection port **11** provides access to vessel **43**. Injection control **9** is attached to drive mechanism **45** which is subsequently linked to shaft **27**. As discussed earlier, the

movement of shaft **27** drives filament **5** forward. Spool **41** stores filament **5** prior to delivery and acts as a filament reservoir as filament **5** is advanced. If only a portion of filament **5** is required, filament **5** may be severed by cutting mechanism **42** activated by cut control **10**.

Fig. 11A is a cross section of the result after the device has been used to coapt the walls of a tubular structure **52**, or vas (as defined above), within the body. The tubular structure **52** may be any within the body such as a ureter, urethra, vein, artery, bowel, esophagus, stomach, oropharynx or sphincter. Other body tissue **54** surrounds wall **53** of tubular structure **52**. Filament balls **51** have been placed on either side of the tubular structure to create an increase in resistance to flow, provide a site for local drug delivery or support internal structures such as valves. Placement of filament balls **51** within exterior body tissue **54** is shown by way of example, while placement within or proximal to wall **53** is also within the scope of the invention.

Fig. 11B illustrates another embodiment of the invention, in which filament injection device **1** is applied in the treatment of an ulcer such as a peptic ulcer of the duodenum, stomach, or lower esophagus. Conduit **6** is shown supplying filament (not shown) into crater **56** of ulcerated mucosa **57** surrounding blood vessel **58**. By inserting the fiber into the vicinity of blood vessel **58**, it is possible to stop the supply of blood to the ulcer.

Fig. 12 illustrates an embodiment of the invention for removing a filament in the body after it has been placed. Cannula **61** is advanced into the center of the filament ball and then hook **62** is pushed forward. Once a strand of the filament has been captured or snagged by the hook **62**, the filament and the device may be withdrawn.

The present invention may be used for purposes other than bulking of tissue. In particular, the device of the present invention may also be used for the delivery of suture for purposes such as sewing, ligation, and anastomosis. In this mode, the device may be passed into and through tissue, advancing a singular loop of suture before being pulled back. As seen in Figs. 13A-13C, the procedure may permit the suture to be passed through and around tissue without the requirement of manipulating a loose needle. Here needle **71** is passed through tissue **72** with the aid of grasper **73**. Once through the tissue, filament **74** is advanced and grasped by grasper **73**; then the needle **71** may be withdrawn. After the filament has been deployed as desired, the filament may be severed, and once the filament is severed, a knot may be tied. Another use is shown in Fig. 7C. Here, several insertions of needle **71** can be performed to create a series of linked loops **75** which can ultimately be tensioned and tied.

Fig. 14 illustrates the mechanism through which particles may be injected into the body, in accordance with another embodiment of the invention, in order to accomplish the same purposes as taught in this specification with respect to the injection of filament. Again, as in the case of filament, the particle may be one of any of the currently available biocompatible materials, including but not limited to silk, plastic, polymer, metal, cells, collagen, bone or other material described above in connection with the definition of the term "filament". Specifically, as with the filament, the material may also be one of any available suture materials such as polyglycolic acid (PGA), polytetrafluoroethylene (PTFE), DACRON™, polypropylene, nylon polyester, silk, polybutylester, stainless steel, titanium, chromic gut, polybutylester, cotton, or silver. Here, particles **80** are shown being injected into a created cavity **86** within the body **87**. Particles **80** are passed down the shaft **81** along with a pressurized fluid **83** from storage chamber **88** propelled by pressure source **84**. The fluid is then withdrawn via channel **82** by suction source **85**. The pressure and suction sources may be manually activated or may be electronically controlled or otherwise controlled. The pressurized fluid may be also a gas like CO_2, but may also be saline, dextrose, antibiotic or other biocompatible agent that acts either passively to assist the particles to reach their destination, or performs another purpose such as providing antibiotic protection, activating the particles once in place, or providing a means through which the particles may be held in one place. The particles may be of any size which permits them to be introduced down the shaft of a cannula, catheter or needle.

Figs. 15A and 15B show respectively a descended bladder of a female subject and the same bladder after it has been elevated by use of a filament implanted in accordance with an embodiment of the invention. In these figures the bladder **91** and bladder neck **93** are shown in relation to the pubic bone **92**, the vagina **94**, uterus **95**, and anus **96**. In accordance with this embodiment, as shown in Fig. 15B, filament **99** is implanted in tissue so as to provide elevation of the bladder in the region of the bladder neck **93**. The filament **99** is inserted using cannula **98** to which is affixed delivery tool **97**. Detailed descriptions of the delivery tool **97** are provided below. It will be appreciated that other organs and tissue may be similarly supported or relocated using similar techniques.

Fig. 16 shows an embolism that has been achieved in a blood vessel by means of a filament implanted in accordance with an embodiment of the invention. Here filament **106** has been inserted to create an embolism in the blood vessel **101**. Insertion of the filament is

achieved first by appropriate placement of guide wire **103** in a manner known in the art. Catheter **102** is equipped with a cutter **104** and a side hole **105** from which emanates the filament **106**. After an appropriate length of filament has been implanted in the blood vessel **101**, the cutter **104** is used to cut the filament at the point where it emanates from the catheter, and the catheter and guide wire are thereupon removed. A technique similar to this may be utilized in other tissue to prevent flow or leakage.

Fig. 17 shows an aneurysm that has been filled by means of a filament implanted in accordance with an embodiment of the invention. In this figure filament **106** is used to fill aneurysm **111** in blood vessel **101**. Again insertion is achieved utilizing guide wire **103** over which catheter **102** is inserted. The catheter **102** is used to carry the filament **106**, which emerges from side hole **105** and is cut, after a desired length has been implanted, by cutter **104**.

Figs. 18A through 26 illustrate various embodiments of the invention for achieving the movement of a filament along a desired path so as to permit implantation of the filament. It will be appreciated that these embodiments, which provide an engine for the advance of filament in a catheter, may be incorporated in a variety of delivery tools. One type of delivery tool may be in the form of a completely hand-held unit, which includes a spool or cartridge of filament, the filament-advance engine, as well as a fitting to receive a catheter or other insertion device. The entire unit may be disposable or it may be provided with features making it able to withstand sterilization in an autoclave or by other means. Similarly, it is within the scope of the present invention to put the filament-advance engine in a first case, along with a cassette or spool of filament, and permit the case to be placed on a table or otherwise suspended or mounted in a convenient location for use. In this connection, there may be attached to the case a disposable cannula for carrying the filament to the site of the operation. The cannula may be fitted with a suitable handle and control arrangement, as well as a tip. The cannula, handle and tip may all be implemented as disposables or alternatively as sterilizable items. The filament advance engine may be motor driven or hand driven. In the event that it is hand driven, power to the device may be provided by successive squeezes of a trigger or lever against a handle for the tool; the extent of the squeeze may regulate the extent of the advance of the filament.

As discussed above, the filament may be a monofilament made, for example, of a suitable polymer such as nylon, polybutylester, or polypropylene. Alternatively the filament

may be braided. In the case of a braided filament and in some instances in the case of a monofilament, the flexibility of the filament may make it difficult to advance, even in a cannula. Accordingly, in an embodiment of the invention, the filament is treated with a suitable stiffening agent, typically at a time prior to placement of the filament in the delivery tool. This stiffening agent is preferably made up of an absorbable material, such as starch, but it is within the scope of the invention to utilize other materials that provide requisite stiffness and avoid the irritation of tissue. The stiffness of a filament may also be varied through temperature-effects in situ, such as by use of the temperature-dependent properties of polymers and other materials, as known to persons skilled in the art.

The filament may be provided to the delivery tool in a spool or other convenient form. In this respect, it should be noted that it is typical for many filament materials to have some shape memory, and the manner in which the filament is spooled can affect the manner in which the filament responds as it emanates from the delivery tool and even as it is being advanced through the delivery tool. Accordingly the spooling of the filament may be implemented in a manner designed to provide characteristics suitable for the particular implantation task at hand. Where it is desired, for example, to have the filament tightly occupy a small volume, the filament may be wound on a spool of small diameter and heated in place on the spool to cause memorization of the small-radius associated with the spool. Note that the small-radius may be retained in shape memory even if the filament must be subsequently be rewound onto a different spool for insertion into the delivery tool. It is also possible, of course, to sterilize the filament after it has been wound onto the spool.

Figs. 18A and 18B illustrate an embodiment for achieving movement of a filament utilizing a pair of conveyor belts symmetrically engaged against the filament. Here the conveyor belts **121** and **122** engage against the filament **123**. The belts are driven by one or more of the pulleys **124** about which they are mounted. The filament **123** is fed through an input conduit **126** into an output conduit **125** that is located preferably close to the location where the filament emerges from the pair of belts so as to prevent bunching. The outer diameter of output conduit **125** may be ground down to allow close proximity between output conduit **125** and conveyor belts **121** and **122**.

Fig. 19 illustrates an embodiment for achieving movement of a filament utilizing a toothed drive wheel against which the filament is engaged by an idler wheel. The toothed drive wheel is shown as item **131** and the idler wheel as item **132**. Also shown are the input

conduit **126** and the output conduit **125**. The outer diameter of output conduit **125** may be ground down to allow close proximity between output conduit **125** and drive wheels **131** and **132**.

Fig. 20 illustrates an embodiment, similar to that of Fig. 19, utilizing a toothed drive wheel against which the filament is engaged by an idler wheel, but wherein the filament is also engaged against the drive wheel by a guide having an arcuate surface that general conforms to the radius of the drive wheel. Here the guide is shown as item **141**, and it replaces input conduit **126**. The advantage of this arrangement is that it increases the length of the filament **123** that is engaged by drive wheel **131** and therefore ensures better traction by the drive wheel **131**.

Figs. 21A and 21B illustrate an embodiment, similar to that of Fig. 19, utilizing a toothed drive wheel **131** against which the filament is engaged by an idler wheel **132**, but wherein the idler wheel at **132** is soft.

Fig. 22 illustrates an embodiment for achieving movement of a filament utilizing a toothed drive wheel against which the filament is engaged by a tubular guide. In this figure the drive wheel **131** operates through a slot formed in the tubular guide **161**. This embodiment has the advantage of achieving a complete merger of the input and output conduits.

Figs. 23A and 23B illustrate an embodiment for achieving movement of a filament utilizing a drive wheel against which the filament is engaged by an idler belt. In this figure the drive wheel **171** is shown to engage the filament **123** against belt **173** that is disposed around pulleys **172**. The filament emerges through exit conduit **125**.

Figs. 24A through 24E illustrate an embodiment for achieving movement of a filament utilizing a pair of axially reciprocating tubular members, within which the filament is disposed, in conjunction with a periodically clamping finger. In these figures the tubular members **181** and **182** operate within sleeve **185**. Tubular member **181** is caused to move within the sleeve **185** carrying the filament **123** with it during the feeding phase. The finger **186** is spring loaded to cause the tip **187** of the finger to press against the filament **123** in channel **189** of the tubular member **181**. During the reset phase, filament **123** is trapped from retrograde movement by finger **186**. In Fig. 24A, the tubular member **181** is fully advanced, having just completed a stroke. In Fig. 24B, the tip **187** of finger **186** has been caused to move away from the filament **123** in channel **189** owing to action of the sliding cam 188. The

disengagement of the finger **186** from the filament permits the tubular member 181 to slide axially to the left in sleeve 185 without causing any motion of the filament in a leftward direction. The assembly consisting of the tubular member **181** and the finger **186** with its cam **188** is thus shown fully retracted in Fig. 24C. In Fig. 24D the cam **188** has been slid to the right, permitting the finger **186** to engage the filament **123** at the tip **187** of the finger. The finger so engaged is shown in Fig. 24D. At this point the tubular member and finger assembly can then advance to the right as shown in Fig. 24A. In order to maintain the shape of the filament **123**, between the termination of the tubular members **181** and **182** is a spring **183** within the sleeve **185**. These springs surround the filament and tend to reduce any bowing of the filament that would prevent transmission of force along its length. Fig. 24E shows the assembly of Figs. 24A through 24D rotated 90°. Here it can be seen that the sliding cam **188** may receive reciprocating power at tab **188a**. A slot **188b** is formed in a portion of the cam through which protrude posts **181a** and **181b** that are coupled rigidly to the tubular member **181**. Accordingly, when the cam is urged to the right and when post **181a** hits the leftmost limit of slot **188b**, the power provided at tab **188a** will cause the tubular member **181** to move to the right. When the post **181b** encounters the rightmost portion of slot **188b**, the tubular member 181 will be moved to the left. This arrangement permits the same reciprocating power at tab **188a** to actuate both the cam **188** and the tubular member **181**. As shown in certain other embodiments, it may be necessary or desirable to provide a suitable arrangement for applying a slight resistance to leftward motion of the filament when the tubular member **123** is undergoing retraction from the fully advanced position.

Figs. 25A through 25E illustrate an embodiment similar to that of Figs. 24A through 24E but in which the coil springs of the latter figures are supplanted by complementary mating extensions of the tubular members. In this case the tubular member **181** includes the extension **191** and the tubular member **182** includes the extension **192**. The strokes for advancing the filament in the case of Figs. 25A through 25D correspond to the strokes described previously in connection with Figs. 24A through 24D. Similarly Fig. 25E corresponds to Fig. 24E. It can be seen in Fig. 25C that as the tubular members **181** and **182** are separated, some guidance for the filament **123** is provided by the extensions **191** and **192** of the tubular members **181** and **182** respectively. Although only a single pair **191** and **192** of extensions are shown, it is within the scope of the present invention to provide a plurality of extensions to each of the tubular members **181** and **182** in such a way that the extensions

meet with each other when the tubular members **181** and **182** are fully advanced to provide the effect of a single conduit; and when the tubular members are separated, a plurality of extensions are present around the end of the tubular member to provide support for the filament.

Figs. 26A and 26B illustrate an embodiment for achieving movement of a filament utilizing a pair of arms that are caused to reciprocate axially while being alternately opened and closed at the opposite ends of each stroke. In this figure are shown arms **201** and **202** that include tips **203** and **204** respectively for pinching filament **123**. Cam assembly **205** is arranged to cause successive opening and closing of the arms **201** and **202** and therefore of the tips **204** and **203**. The cam assembly **205** is also configured to cause reciprocating motion of the arm assembly in the left-right direction, that is, in the direction of the length of filament **123**. Furthermore, the cam assembly **205** is configured so that a cycle of operation causes the tips **203** and **204** to grab the filament **123** when the arm assembly is in its leftmost position and to retain grip on the filament until the arm assembly has reached its rightmost position. At this position, on the arm assembly is caused to open, whereupon grip of the tips **204** and **203** on the filament **123** is released. In Figs. 26A and 26B can be seen spool **207** of material constituting filament **123** as well as output conduit through which the filament **123** runs after exiting from the tips **204** and **203**. In the output conduit **207** is a channel into which protrudes pawl **206**. The pawl is angled in such a way that it offers little resistance to forward motion of the filament, but offers considerable resistance to rearward motion of the filament (forward motion being to the right). If it is desired to retract the filament **123** the arms **201** and **202** may be opened and the spool **207** may be powered to effectuate rewinding, in which case the pawl **206** may also be optionally disengaged from the filament. Alternatively, the spool **207** may be driven in reverse through a clutch arrangement and the advance mechanism constituting the two arms may be run backwards.

In the case of the filament-advance engines described above, it is possible to monitor a number of parameters including the number of revolutions of the filament spool, or (directly) the length of filament being unspooled, as well as the number of reciprocations or drive movements associated with attempts at moving the filament. The drive movements can be matched against actual filament movement in order to determine whether slippage is taking place. If it is determined that slippage is present, an alarm state may be entered to permit appropriate corrective action.

Figs. 27A through 30D illustrate embodiments of the invention in which a region proximate to a tip of a cannula carrying a filament is provided with an arrangement, for cutting the filament, utilizing a concentrically disposed member and a window in both members through which the filament is placed and severed.

Figs. 27A and 27B illustrate an embodiment wherein the outer member is pulled proximally with respect to the inner member to achieve cutting. In Fig. 27A there is shown inner member **212** in relation to outer member **213**. Filament **211** is carried in the lumen of the inner member **212** and emanates from window **214**. In Fig. 27B the outer member **213** is pulled proximally with respect to the inner member **212** so that a scissors action results from the passage of edge **214** on the outer member **213** by the edge **215** of the inner member **212**. The result is the cutting of filament **211** at the intersection of edges **214** and **215**. The relative motion of the inner member and outer member **213** causes the window **216** in the outer member to cease to coincide with the window **214** of the inner member. It should be noted that design of the edges **214** and **215** may be implemented in a variety of fashions. In Figs. 27A and 27B, **214** is beveled and **215** is straight. Alternatively **215** may be beveled and **214** may be straight. In fact a successful scissors action may be achieved when windows **214** and **215** are both straight, particularly if the windows **214** and **216** are configured in such a way that the intersection of the edges **214** and **215** moves somewhat helically as outer member **213** is moved proximally.

Figs. 28A and 28B illustrate an embodiment wherein the outer member is pushed distally with respect to the inner member to achieve cutting. In this figure the design is similar to that shown in Figs. 27A and 27B. Here pushing the outer member **221** distally causes passage of the beveled edge **222** of outer member **221** by the straight edge **223** of inner member **212** and consequent cutting of filament **211**. Equivalently, edge **223** may be beveled and **222** may be straight, or both may be beveled, or neither may be beveled.

Figs. 29A through 29C illustrate an embodiment wherein the inner and outer members are rotated with respect to one another to achieve cutting. The outer member **231** is permitted to rotate around inner member **212** to cause cutting of the fiber **211** emerging through the window **232**. The effect of the rotation can be seen in the cross section taken at **BB** and shown in Figs. 29B and 29C. The effect of the rotation is to cause edge **233** of outer member **231** to slice the filament **211** against the edge **234** of inner member **212**.

Figs. 30A through 30D illustrate the way a tip, having a cutting arrangement of one of

the types described above, may be employed in conjunction with a suitable window to prevent the presentation of undue pressure, by the distal end of the filament, on tissue of the subject on whom the invention may be used. In Figs. 30A through 30D is shown a push cutter arrangement similar to that shown and discussed in connection with Figs. 28A and 28B. There is thus an outer member **221** having a bevel **222** and an inner member **212**. A window **243** is provided in the inner member to permit the emergence of a loop of filament **211**. The end of the filament may be suitably captured in region **242** near the tip **241** of inner member **212**. Using a filament-advance engine in accordance with a suitable embodiment such as described above, the filament may be caused to leave the exit window **243** while keeping the end of the filament engaged near the tip **241**. The advantage of following such a procedure is that the loop of filament material will exert less pressure on tissue than would a free end; in this way the risk of lesion to surrounding tissue is reduced. In the course of advancing the filament into tissue, the end of the filament will eventually leave the tip region **242**; however at this point, owing to the presence of a substantial portion of filament length already present, the forces associated with movement at the end of the filament are dramatically reduced. After a desired quantity of filament has been implanted, the outer member **221** is used to cause cutting of the filament **211**. Cutting is initiated therefore by moving outer member **221** distally, as shown in Fig. 30C. In figure 30D, the filament **211** has been cut, and it can be seen that by further advancing the filament. The end will again be engaged in tip region **242**, so that when desired the window **243** can again be opened by withdrawal of the outer member **221** and the process begun anew.

It will be appreciated that the size of the exit window **243** may be selected to take into account the particular nature of the implantation desired and the filament employed. For example, if it is desired that the material be concentrated in a very small region or if the filament is very flexible, then a smaller exit window may be appropriate, whereas if a larger region is to be treated or a stiffer filament is used, a larger exit window will be indicated.

In general, when a guide wire is utilized in connection with a cannula used for filament implantation herein, the guide wire may be utilized in a separate lumen of the cannula. Alternatively, it is within the scope of the present invention to utilize a common lumen for both the guide wire and the filament.

Figs. 31A and 31B, and 32A and 32B, illustrate a possible configuration for a case for an embodiment similar to that of Figs. 26A and 26B. In this configuration a cannula for

insertion of the filament may be attached at fitting **251**, and a handle **253** for actuating a cutter is also provided. A cable assembly **254** is removably attachable to the body of **255** to supply rotational power to the tool. Knob **252** is coupled to an internally located spool of filament.

The described embodiments of the inventions are intended to be merely exemplary and numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

Claims

What is claimed is:

1. A method for modifying a tissue property of a subject, the method comprising:

a. providing a quantity of filament;

b. opening a portal in the body of the subject;

c. inserting the filament through the portal into a region in the vicinity of the tissue; and

d. localizing the filament in the region so as to modify the tissue property.

2. A method according to claim 1, wherein the property includes at least one of the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue.

3. A method for bulking tissue of a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into a region in the vicinity of the tissue; and

c. localizing the filament in the region so as to achieve bulking of the tissue.

4. A bulking method according to claim 3, wherein the step of inserting includes the step of introducing the filament with the aid of an endoscope.

5. A bulking method according to claim 3, wherein the step of inserting includes the step of introducing the filament with the aid of a laparoscope.

6. A bulking method according to claim 3, further comprising the step of driving fluid through the portal into the tissue to dilate the region to be occupied by the filament.

7. A method for coapting walls of a vas to increase the resistance to flow of a bodily material within the vas, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into the vicinity of the wall of the vas.

8. A method for occluding a vas of a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into the vas; and

c. localizing the filament in a region so as to achieve the occlusion of the vas.

9. An occluding method according to claim 8, wherein the step of providing filament further comprises the step of training the filament to take a preset shape.

10. An occluding method according to claim 8, wherein the step of providing filament

further comprises the step of providing filament that has been coated with an clotting compound.

11. A method for preventing pregnancy in a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into a region in the vicinity of the fallopian tube of the subject; and

c. localizing the filament in the region so as to achieve the occlusion of the fallopian tube.

12. A method for sterilizing a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into a region in the vicinity of the ductus deferens of the subject; and

c. localizing the filament in the region so as to achieve the occlusion of the ductus deferens.

13. A method for clotting of an ulcer fed by a blood vessel, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into a region in the vicinity of the blood vessel; and

c. localizing the filament in the region so as to stop the supply of blood to the ulcer.

14. An ulcer clotting method according to claim 13, wherein the step of providing filament further comprises the step of preloading the filament with at least one therapeutic agent.

15. An ulcer clotting method according to claim 13, wherein the step of providing filament includes the step of providing electrically conducting filament and the method further comprises the step of applying radio-frequency energy for heating the filament.

16. A method of inserting a filament into the body, the method comprising:

a. providing a filament having an end with shape memory;

b. opening a portal in the body of the subject;

c. inserting the filament through the portal; and

d. causing the filament end to assume the shape in its memory.

17. A method for treating an aortic aneurism having an aneurysmal pocket, the method

comprising:

a. delivering a stent graft percutaneously;

b. providing a quantity of filament;

c. inserting the filament into the aneurism; and

d. localizing the filament in a region of the aneurysm so as to clot off the aneurysmal pocket .

18. A method for treating a bleeding esophageal varix in a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into a region in the vicinity of the bleeding varix; and

c. localizing the filament in the region so as to occlude the bleeding varix.

19. A method for treating a bleeding esophageal varix according to claim 18, wherein the step of providing filament further comprises the step of providing filament preloaded with at least one therapeutic agent.

20. A method for treating a bleeding esophageal varix according to claim 18, wherein the step of providing filament includes the step of providing electrically conducting filament and the method further comprises the step of applying radio-frequency energy for heating the filament.

21. A method for providing chemotherapy in a subject having malignant tissue, the method comprising:

a. providing a quantity of filament preloaded with at least one therapeutic agent;

b. inserting the filament into a region in the vicinity of the malignant tissue; and

c. localizing the filament in the region.

22. A method for releasing a drug into a subject, the method comprising:

a. providing a quantity of filament;

b. preloading the filament with at least one therapeutic agent; and

c. inserting the filament into the body of the subject.

23. A method for catalyzing biochemical reactions in the body of a subject, the method comprising:

a. providing a quantity of filament having requisite catalytic properties; and

b. inserting the filament into the body of the subject.

24. A method for monitoring of biochemical processes in situ, the method comprising:

a. providing a quantity of filament;

b. preloading the filament with at least one diagnostic agent;

c. inserting the filament into the body of the subject; and

d. monitoring the response of the agent.

25. A method for providing birth control in a subject, the method comprising:

a. providing a quantity of filament;

b. preloading the filament with at least one contraceptive agent; and

c. inserting the filament into the body of the subject.

26. A method for supporting cell growth in a subject, the method comprising:

a. providing a quantity of filament;

b. inserting the filament into the subject; and

c. localizing the filament in a reticulate manner so as to form a matrix; and

d. allowing the entrance of cells into the matrix.

27. A method as in any one of the preceding claims further comprising the step of injecting a fluid into the body of the subject in conjunction with the filament.

28. A method for sewing tissue, the method comprising:

a. providing a quantity of filament;

b. feeding an end of the filament into a hollow shaft having a tip;

c. inserting the hollow shaft into the tissue;

d. advancing the filament along the shaft into the tissue; and

e. binding the filament so as to suture the tissue.

29. A method for sewing tissue according to claim 30, wherein the hollow shaft of steps (b), (c), and (d) has a longitudinal axis and the tip is deformed so as to lie off the axis to facilitate curving the path of the filament into the tissue.

30. A method for modifying a tissue property of a subject, the method comprising:

a. providing a quantity of filament;

b. feeding an end of the filament into a hollow shaft having a tip;

c. inserting the hollow shaft into a region that includes at least a portion of the tissue;

d. advancing the filament along the shaft into the tissue; and

e. localizing the filament in the region so as to modify the tissue property.

31. A method according to claim 32, wherein at least a portion of the shaft includes a

passageway, and the step (b) includes the step of advancing the filament through the passageway.

32. A method for delivering anesthesia into a tissue comprising the steps of:

a. providing a quantity of filament;

b. preloading the filament with at least one liquid anesthetic agent;

c. feeding an end of the filament into a hollow shaft having a tip;

d. inserting the hollow shaft into a region that includes at least a portion of the tissue;

e. advancing the filament along the shaft into the tissue.

33. A method as in any one of the preceding claims, wherein the filament is a length of suture.

34. A method as in any one of the preceding claims further comprising the step of severing the filament such as to provide a desired length of filament within the body of the subject.

35. A method according to claim 34, wherein the step of severing the filament includes determining the desired length of the filament during a clinical procedure.

36. A method for delivering a stent into a vas of a body, the method comprising:

a. preloading the stent into a shaft;

b. inserting the shaft into the vas;

c. advancing a filament along the shaft into the body so as to propel the stent in advance of the filament; and

d. retracting the filament.

37. A method for modifying a tissue property of a subject, the method comprising:

a. providing a quantity of suture material in particulate form;

b. suspending the suture material in a liquid carrier to create a suture suspension;

c. opening a portal in the body of the subject; and

d. inserting the suture suspension through the portal into a region that includes at least a portion of the tissue.

38. A method according to claim 37, wherein the property includes at least one of the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue.

39. A method for removing filament from a site in the body comprising:

a. inserting a hollow shaft into the site;

b. hooking the filament with a hooked tool;

c. withdrawing the filament via the hollow shaft.

40. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end; and

b. a feeding mechanism for supplying the filament incrementally along the axis of the conduit so as to emerge from the distal end into the site in a manner such that support is provided across all lengths of the filament longer than three times the diameter of the filament.

41. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end;

b. an inner cannula having an inner diameter corresponding generally to the diameter of the filament;

c. a mounting arrangement permitting axial movement of the inner cannula; and

d. an actuator mechanism for urging the inner cannula in axial reciprocation consisting of forward motion and retrograde motion with respect to the mounting arrangement.

42. A device according to claim 41, wherein the inner diameter of the inner cannula is approximately equal to the diameter of the filament.

43. A device according to claim 41, wherein the mounting arrangement includes an outer cannula disposed coaxially with and external to the inner cannula.

44. A device according to claim 41, wherein the feeding mechanism further comprises a gripper for grasping the filament synchronously with forward motion of the inner cannula.

45. A device according to claim 41, wherein the feeding mechanism further comprises a second gripper acting out of phase with the first gripper for retaining the filament during retrograde motion of the inner cannula.

46. A device according to claim 41, wherein the feeding mechanism further comprises a brake for retaining the filament during retrograde motion of the inner cannula.

47. A device according to claim 41, wherein the inner cannula comprises distinct distal and proximal segments.

48. A device according to claim 41, further comprising a containment spring for retracting the distal segment of the inner cannula toward the proximal segment of the inner cannula during retrograde motion of the distal segment of the inner cannula.

49. A device according to claim 41, wherein the mounting arrangement includes a tip for penetrating body tissue.

50. A device according to claim 41, wherein the mounting arrangement further comprises a window, disposed proximally to the tip of the mounting arrangement and having a distal edge, for feeding the filament into the site.

51. A device according to claim 41, wherein the device further comprises a rotation arrangement for holding the mounting arrangement in a chosen azimuthal angle with respect to the axis of the conduit.

52. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end;

b. a plurality of conveyor belts engaged against the filament; and

c. at least one pulley for moving the conveyor belts.

53. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end;

b. a toothed wheel for advancing the filament; and

c. an idler wheel for retaining the filament in contact with the toothed wheel.

54. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end;

b. a first and second strut for holding the filament against the wall of the conduit;

c. a reciprocating shaft disposed along the wall of the conduit having a head articulated downward from a bend in the shaft and a channel disposed

proximally with respect to the head;

d. a partial pivot disposed across the conduit in a sense perpendicular to the axis of the conduit and distally with respect to the head of the shaft for forcing the shaft head into engagement with the filament; and

e. a mechanism for driving the shaft in an advancing direction such that the filament is advanced into the tissue until the channel of the reciprocating shaft aligns with the partial pivot, permitting it to spring back into its original shape and to disengage the filament.

55. A device as in any one of claims 40, 41, or 52-54 inclusive, wherein the conduit includes one of a rigid, semi-rigid, and flexible tubular structure.

56. A device as in any one of claims 40, 41, or 52-54 inclusive, further comprising:

a. an inlet for receiving fluid;

b. a channel for directing the flow of fluid toward the site; and

c. a fluid control for regulating the injection of fluid into the channel.

57. A device according to claim 56, wherein the channel is identical to the conduit inserted into the site.

58. A device as in any one of claims 40, 41, or 52-54 inclusive, further comprising a storage arrangement for storing filament before it is supplied by the feeding mechanism.

59. A device according to claim 58, wherein the storage arrangement is a spool.

60. A device as in any one of claims 40, 41, or 52-54 inclusive, further comprising a rewind mechanism for retracting filament from the site.

61. A device as in any one of claims as in any one of claims 40, 41, or 52-54 inclusive, further comprising a counter for tracking the length of filament which has been fed into the body site.

62. A device as in any one of claims 40, 41, or 52-54 inclusive, further comprising a filament cutter.

63. A device according to claim 62, wherein the filament cutter comprises:

a. a torquable head, disposed adjacent to the distal end of the conduit, having a rotation axis coincident with the axis of the conduit and an off-axis window for passing the filament into the site in the body;

b. a shearing surface disposed on at least one of the distal end of the conduit and

the torquable head such that rotation of the torquable head severs the filament; and

c. a means for rotating the torquable head about the rotation axis of the torquable head.

64. A device according to claim 63, wherein the means for rotating the torquable head is a torque wire disposed along the axis of the conduit.

65. A device according to claim 41, further comprising a filament cutter, the filament cutter comprising:

a. a stop disposed within the mounting arrangement proximally to the distal end of the mounting arrangement; and

b. a sharpened edge disposed on at least one of the inner cannula and the stop such that motion of the inner cannula against the stop causes cutting of the filament.

66. A device according to claim 50 further comprising a filament cutter having a mechanism for driving the inner cannula past the distal edge of the window of the mounting arrangement in such a manner as to cause shearing of the filament.

67. A device according to claim 40, 41, or 52-54 inclusive, further comprising a motor for repetitively cycling the feeding mechanism.

68. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end; and

b. a feeding mechanism for supplying the filament along the axis of the conduit so as to emerge from the distal end; and

c. a filament cutter for shearing the filament.

69. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end; and

b. a feeding mechanism for supplying the filament continuously along the axis of the conduit so as to emerge from the distal end; and

c. a filament cutter for shearing the filament.

70. A device for inserting a filament having a diameter into a site in the body of a subject, the device comprising:

a. a conduit having an axis, an interior wall, a distal end for inserting into the site, and a proximal end; and

b. a feeding mechanism for supplying the filament incrementally along the axis of the conduit so as to emerge from the distal end; and

c. a filament cutter for shearing the filament.

71. A device for removing a filament from a site in the body of a subject, the device comprising:

a. a conduit having a distal end for inserting into the site; and

b. a hook for snagging and withdrawing the filament through the conduit.

72. A stent for modifying a tissue property of a subject, the stent comprising at least one strand of filament localized in a region in the vicinity of the tissue.

73. A stent according to claim 72, wherein the property includes at least one of the mass, bulk, orientation, rigidity, flexibility, springiness, and permeability of the tissue.

74. A stent according to claim 72, wherein the stent is interstitial.

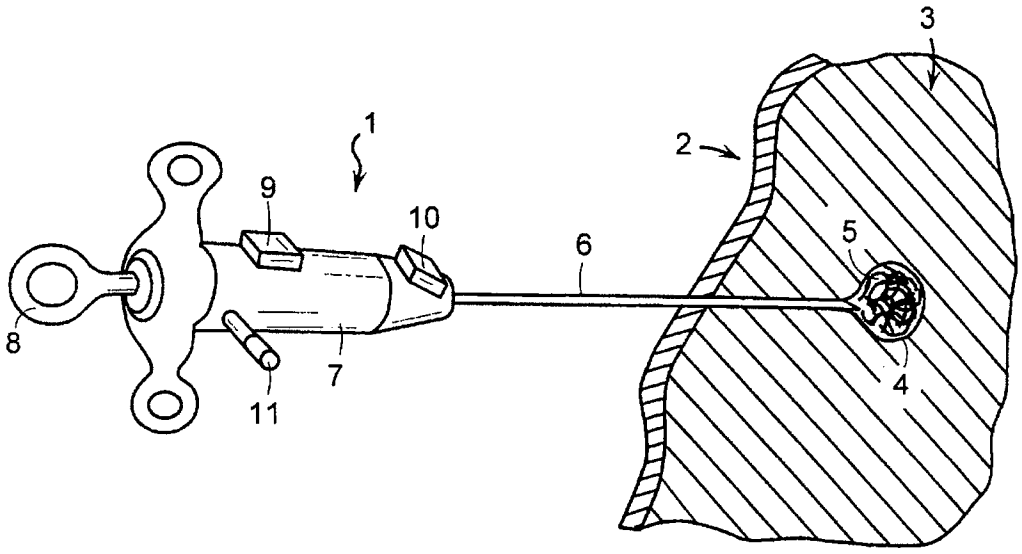


FIG. 1

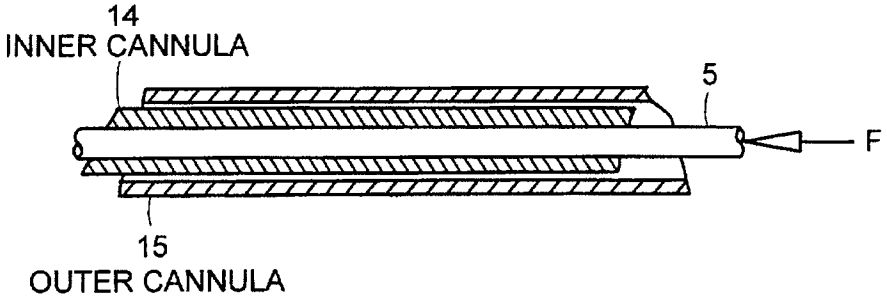


FIG. 2

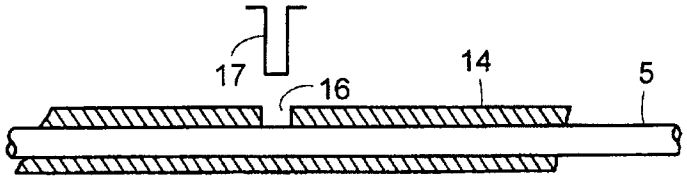


FIG. 3A

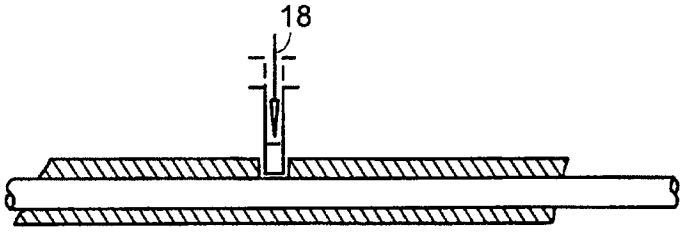


FIG. 3B

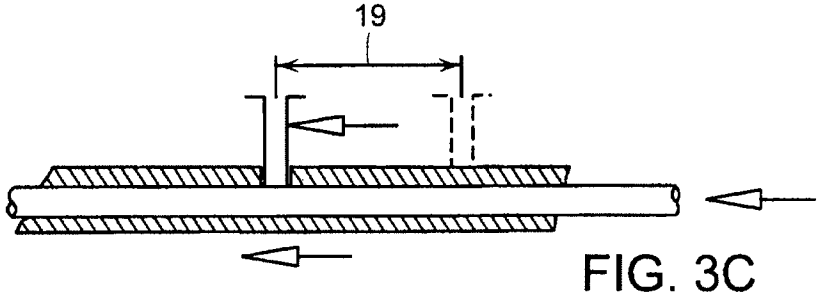


FIG. 3C

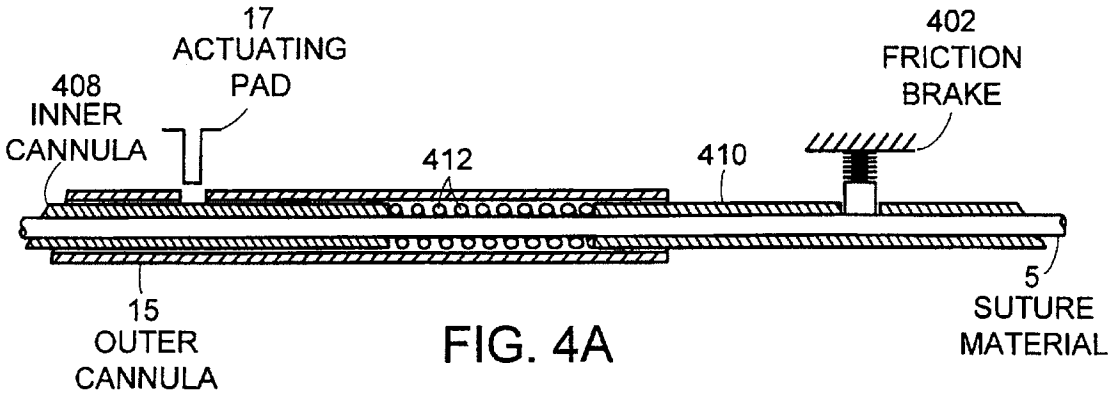


FIG. 4A

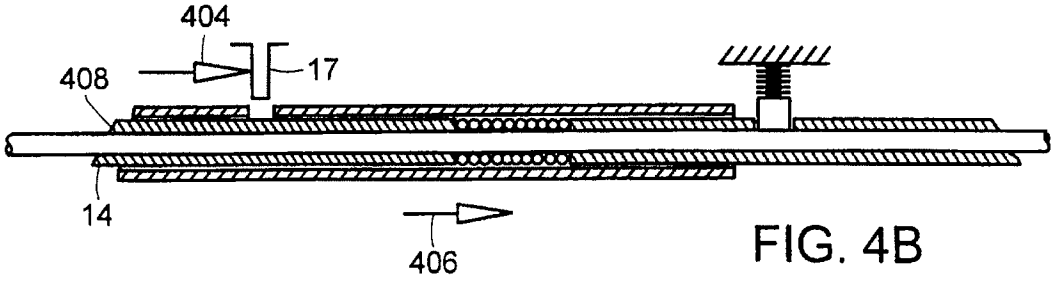
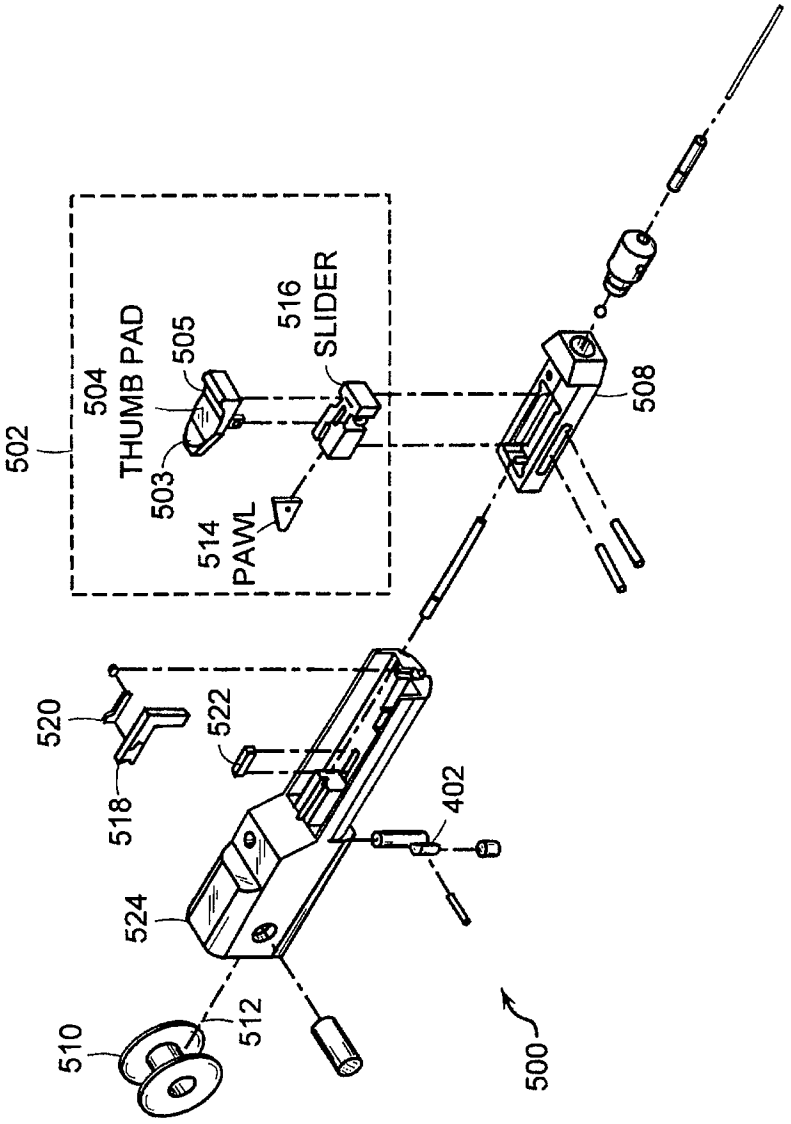


FIG. 4B


502
504
THUMB PAD
505
503
516
SLIDER
514
PAWL
508
520
522
518
402
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512
510
500

FIG.5

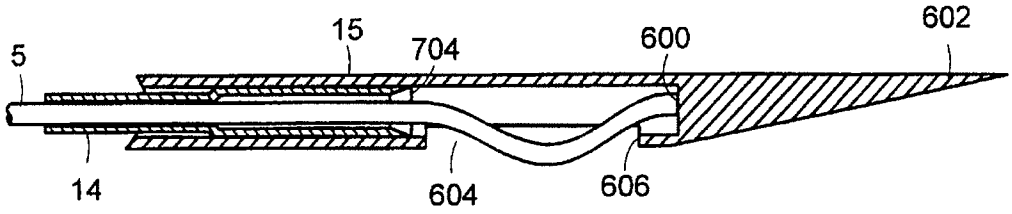

FIG. 6

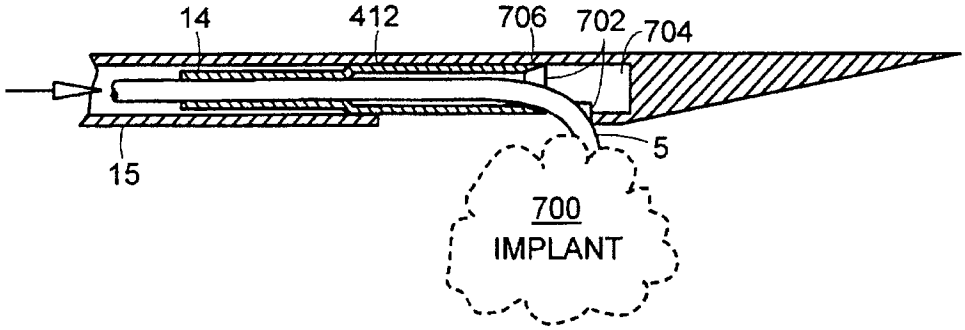

FIG. 7A

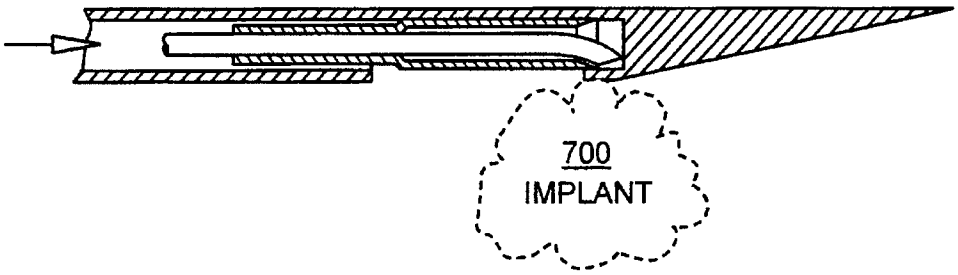

FIG. 7B

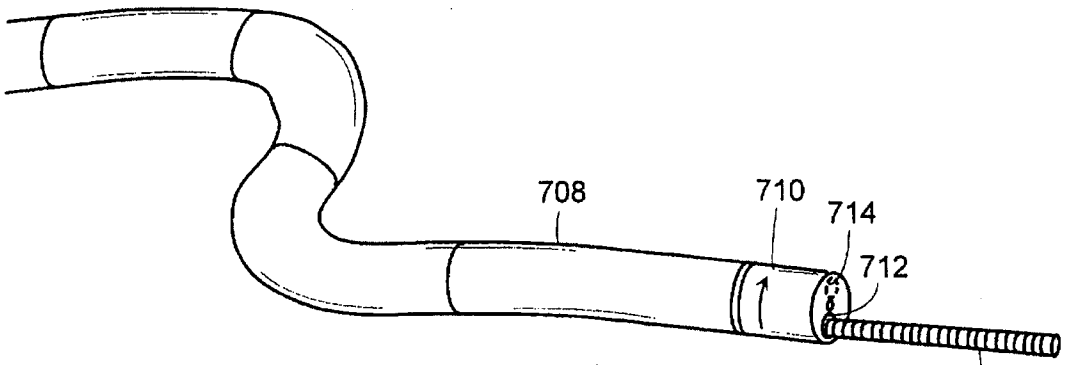

FIG. 7C

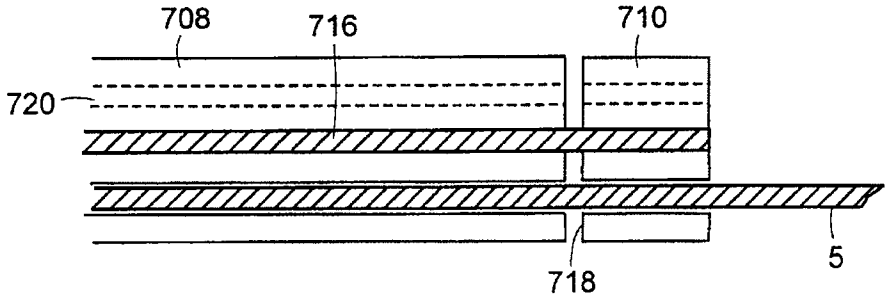

FIG. 7D

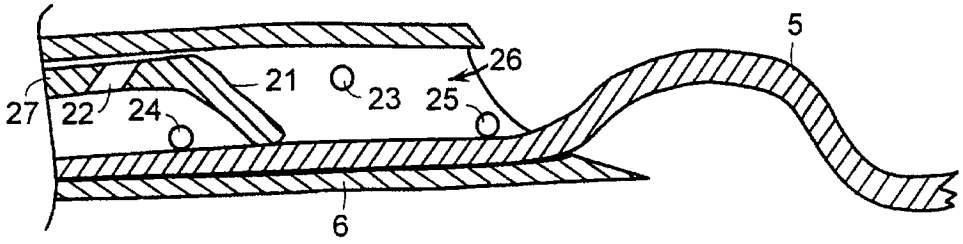

FIG. 8

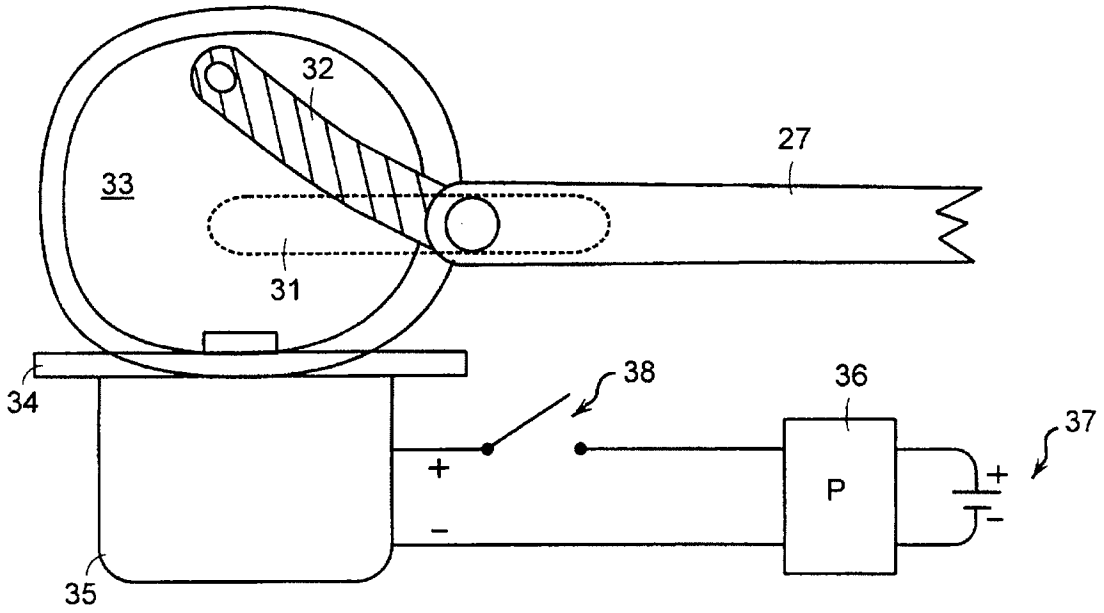

FIG. 9

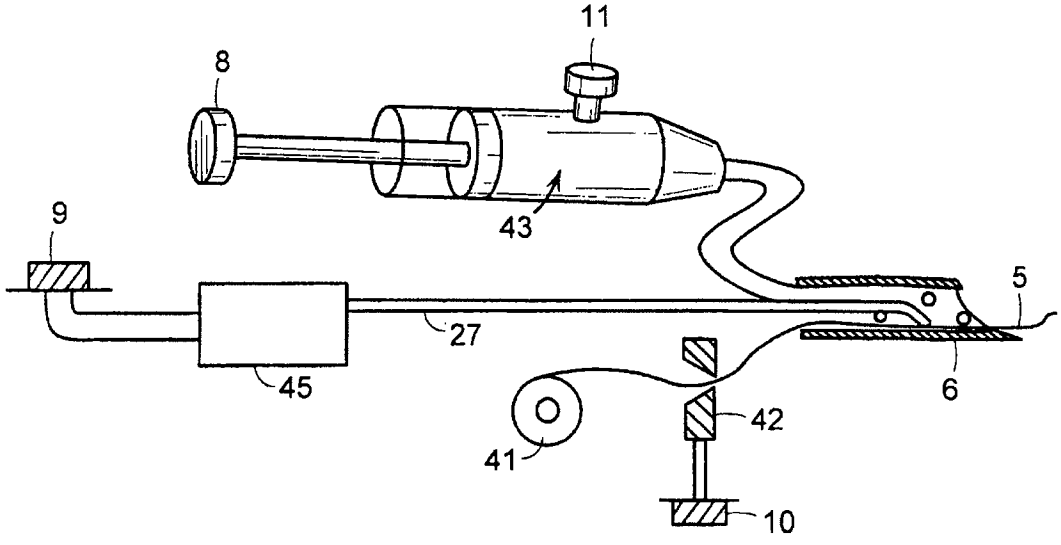

FIG. 10

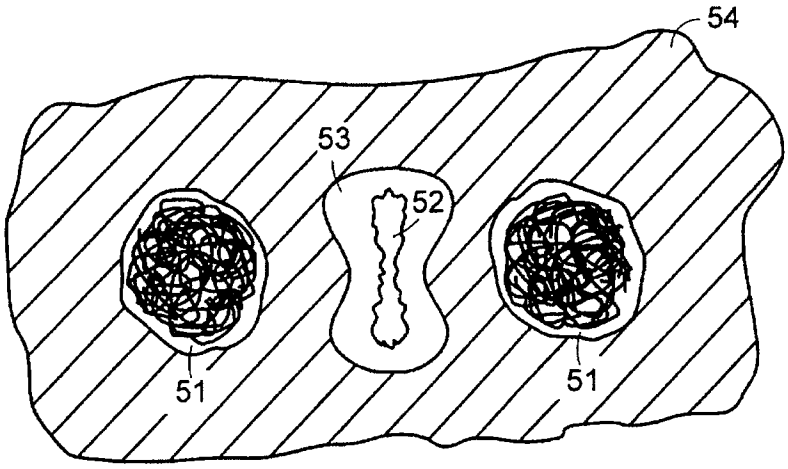

FIG. 11A

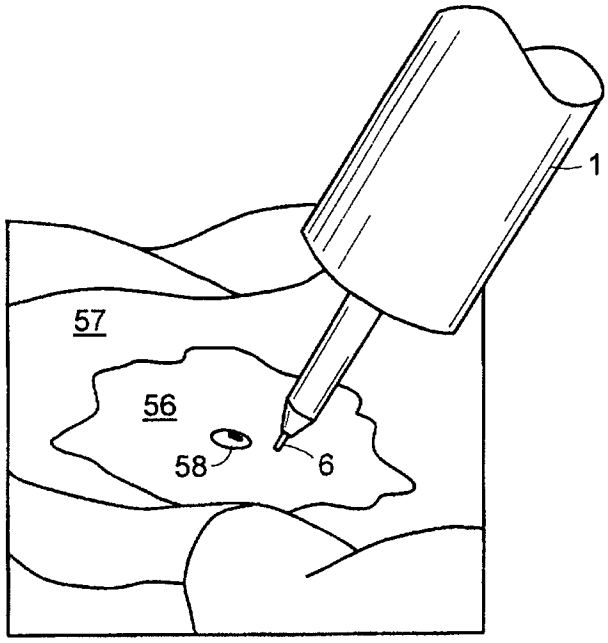

FIG. 11B

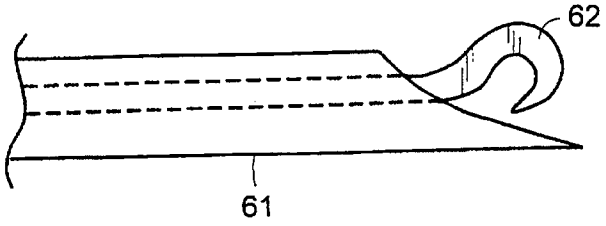

FIG. 12

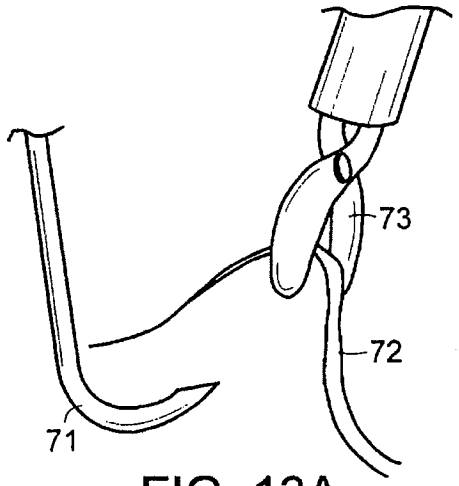

FIG. 13A

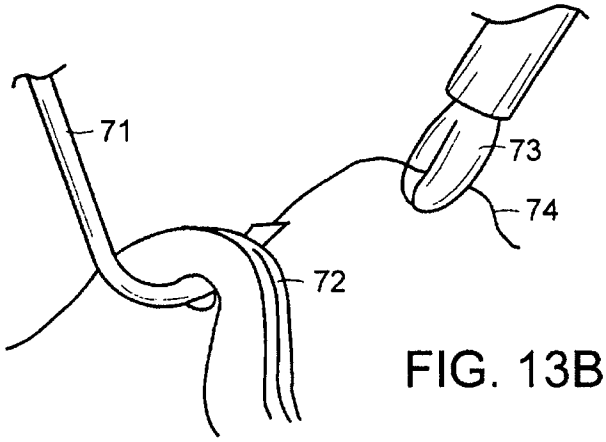

FIG. 13B

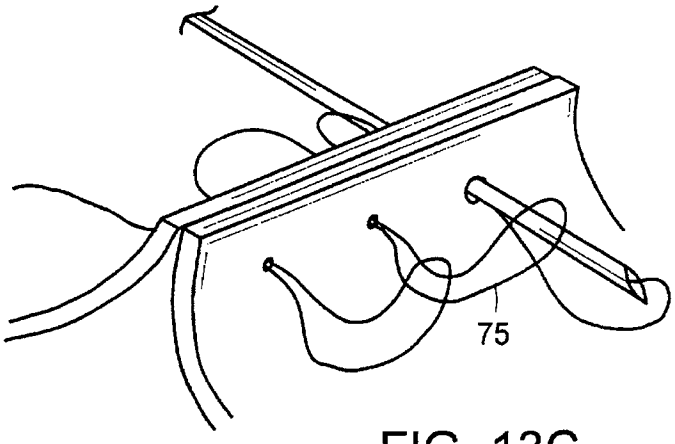

FIG. 13C

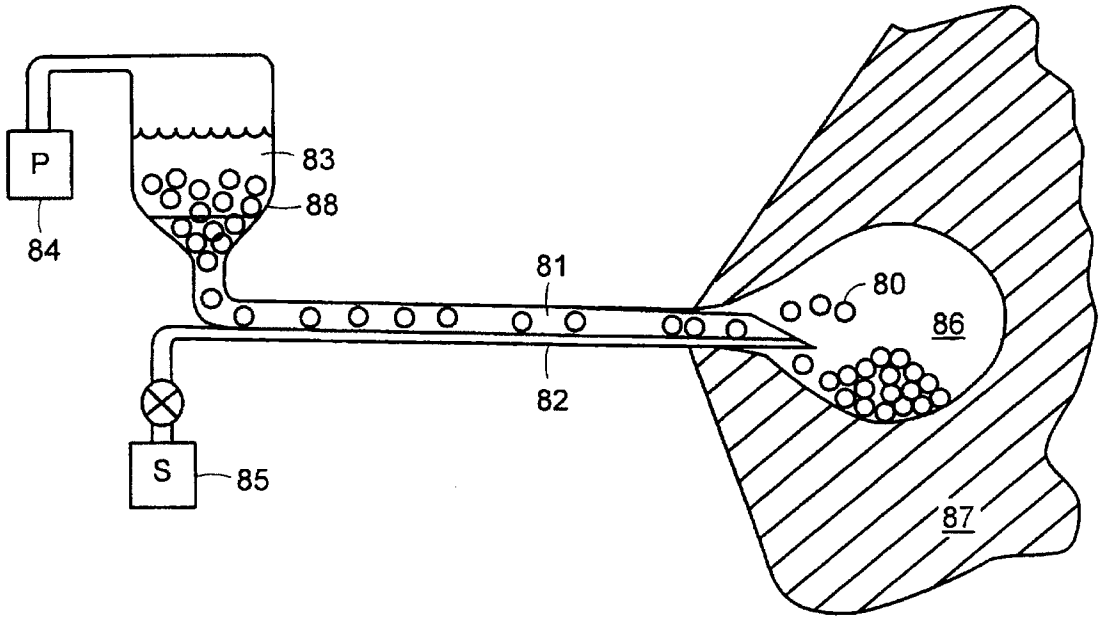

FIG. 14

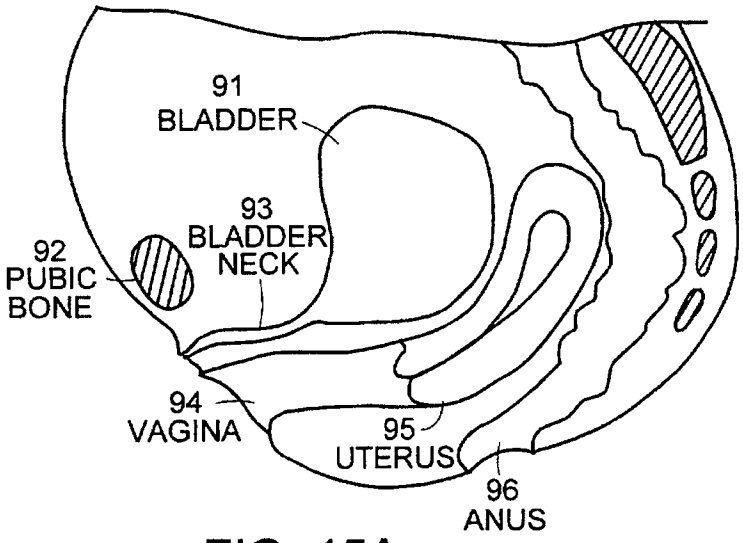

FIG. 15A

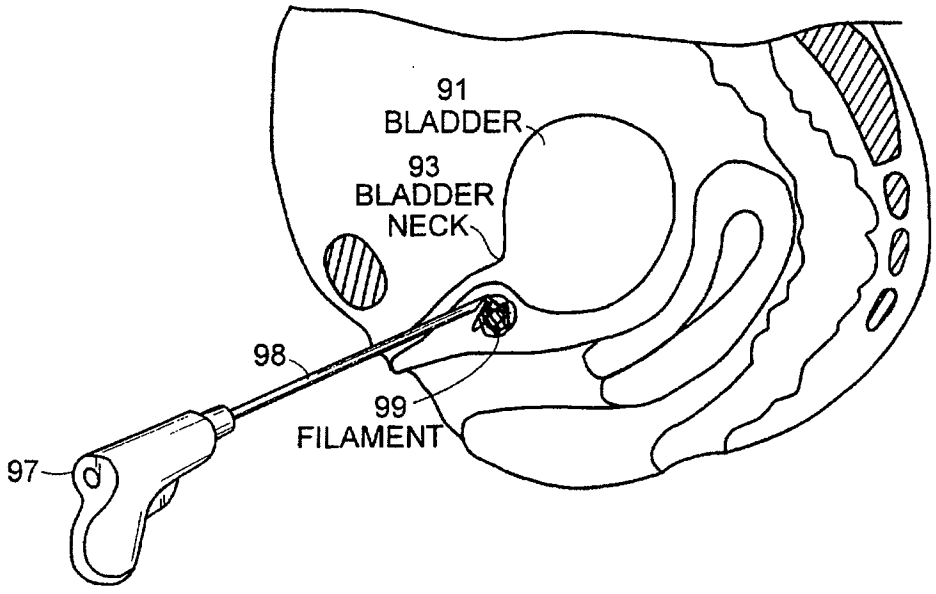

FIG. 15B

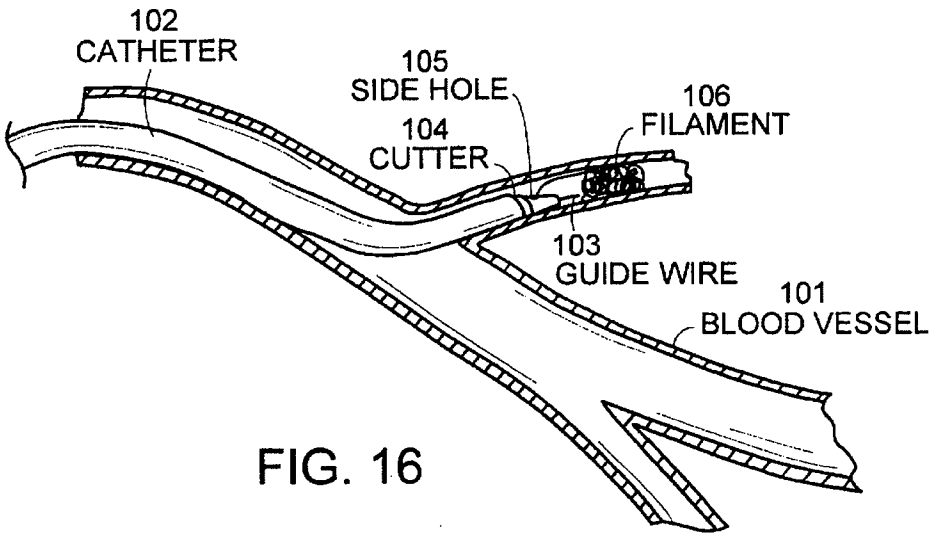
102
CATHETER
105
SIDE HOLE
104
CUTTER
106
FILAMENT
103
GUIDE WIRE
101
BLOOD VESSEL

FIG. 16

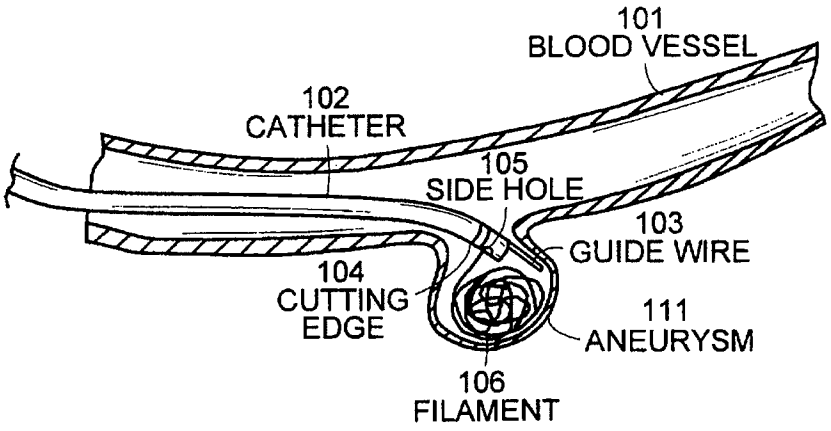
101
BLOOD VESSEL
102
CATHETER
105
SIDE HOLE
103
GUIDE WIRE
104
CUTTING
EDGE
111
ANEURYSM
106
FILAMENT

FIG. 17

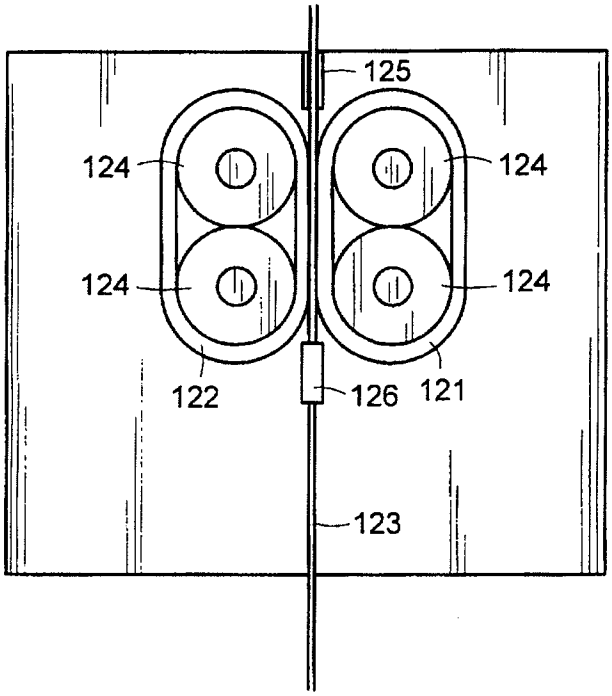

FIG. 18A

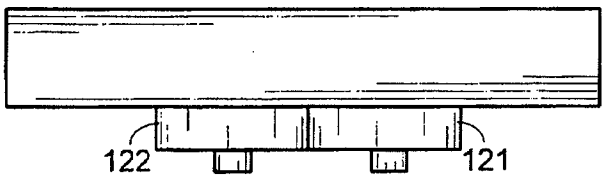

FIG. 18B

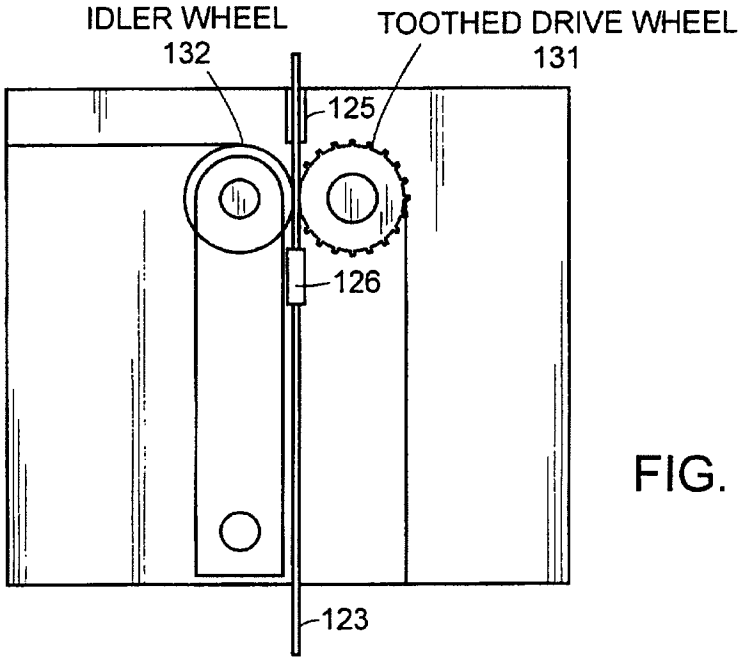
IDLER WHEEL
132
TOOTHED DRIVE WHEEL
131
125
126
123

FIG. 19

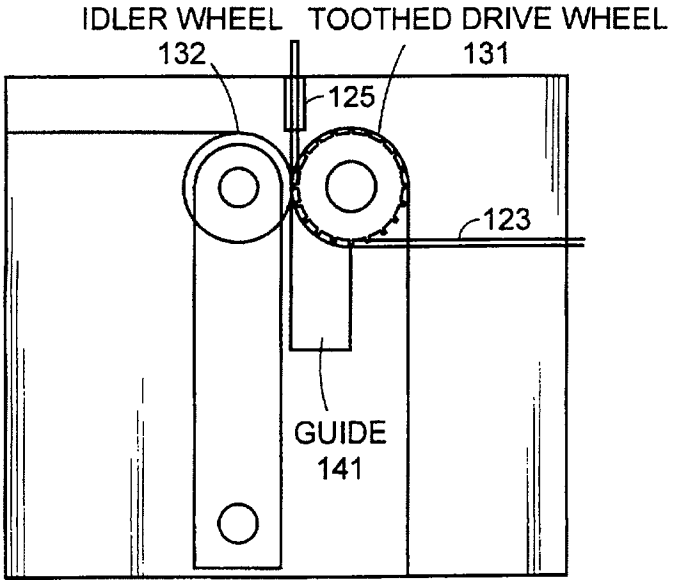
IDLER WHEEL
132
TOOTHED DRIVE WHEEL
131
125
123
GUIDE
141

FIG. 20

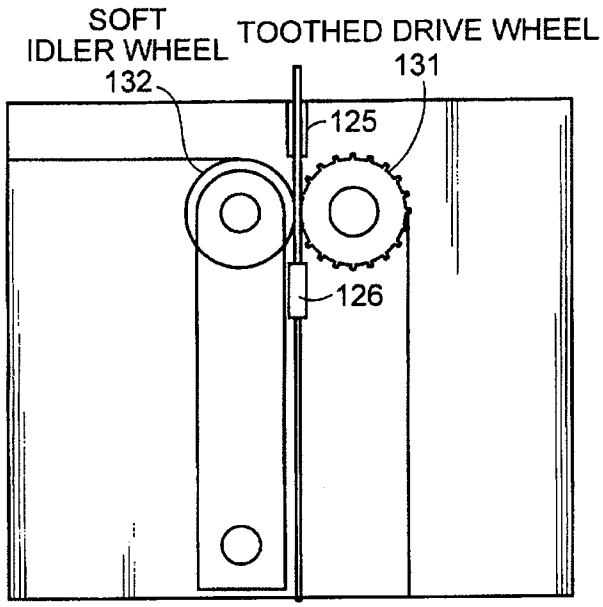

FIG. 21A

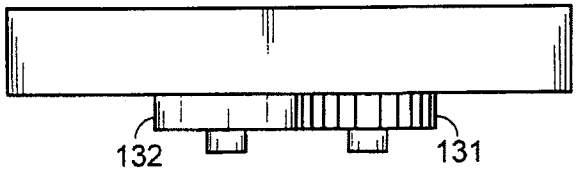

FIG. 21B

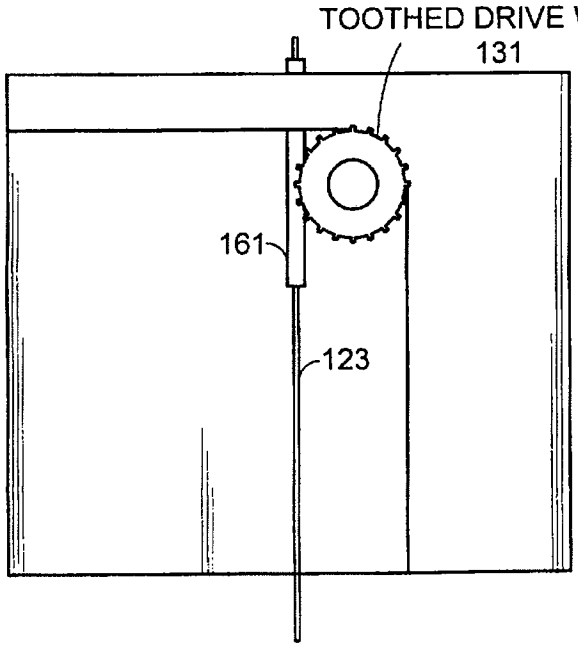

FIG. 22

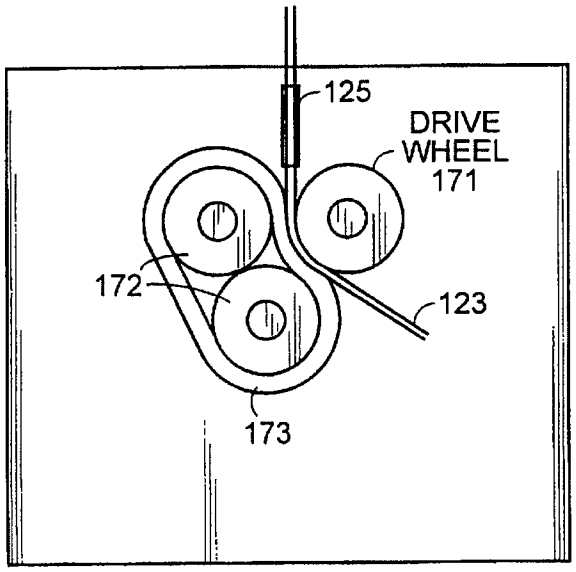

FIG. 23A

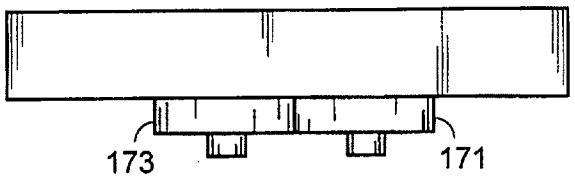

FIG. 23B

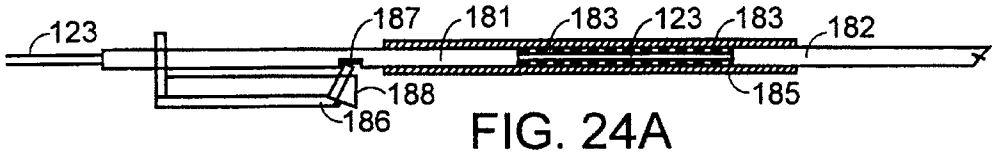

FIG. 24A

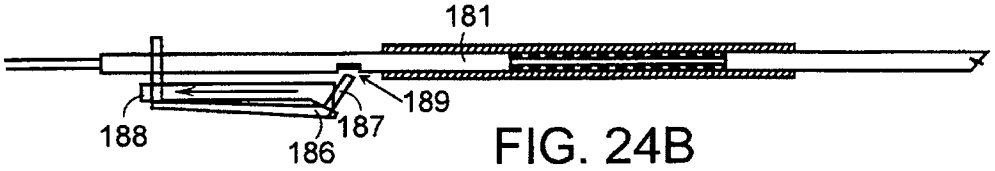

FIG. 24B

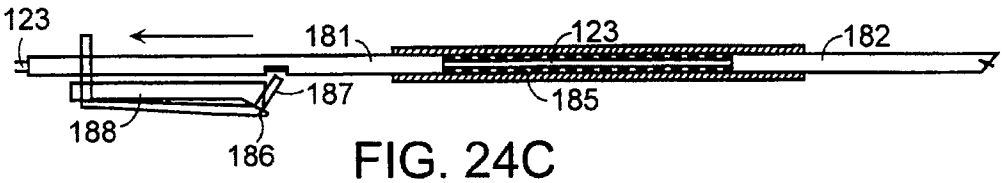

FIG. 24C

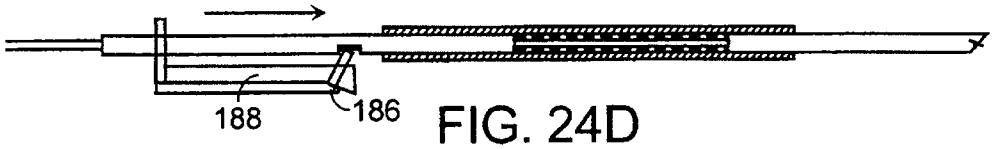

FIG. 24D

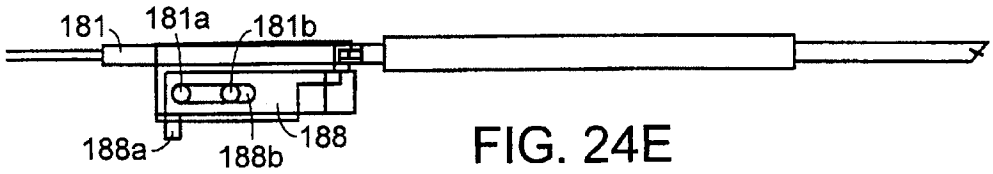

FIG. 24E

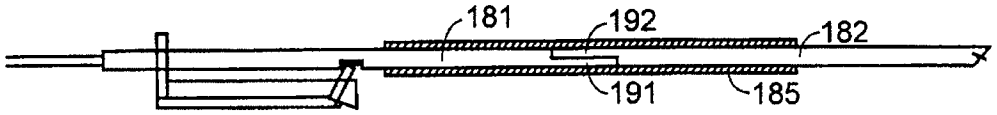

FIG. 25A

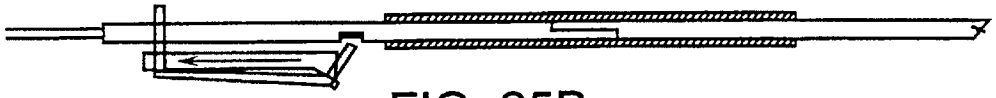

FIG. 25B

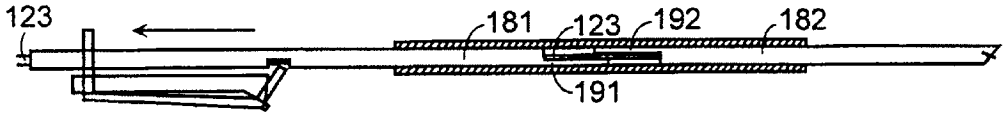

FIG. 25C

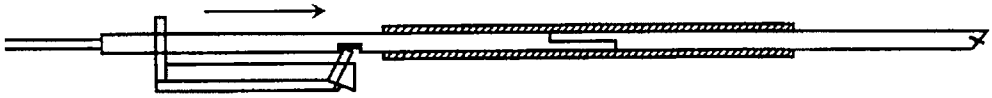

FIG. 25D

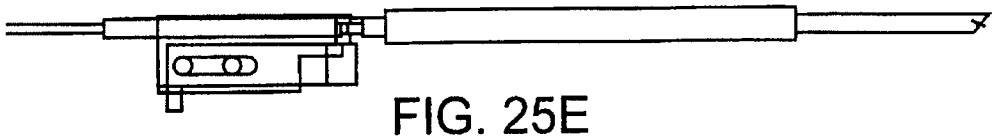

FIG. 25E

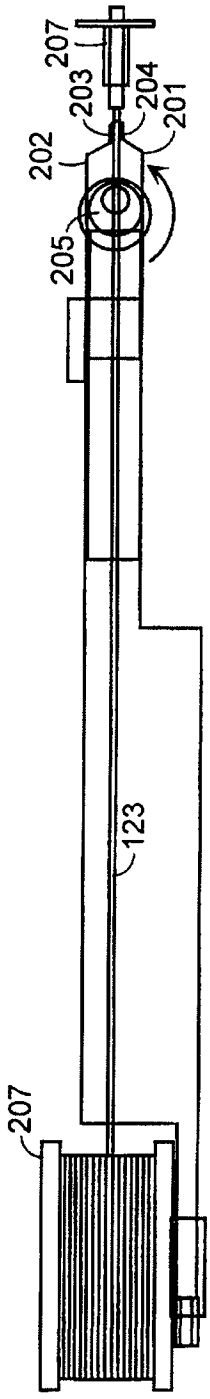

FIG. 26A

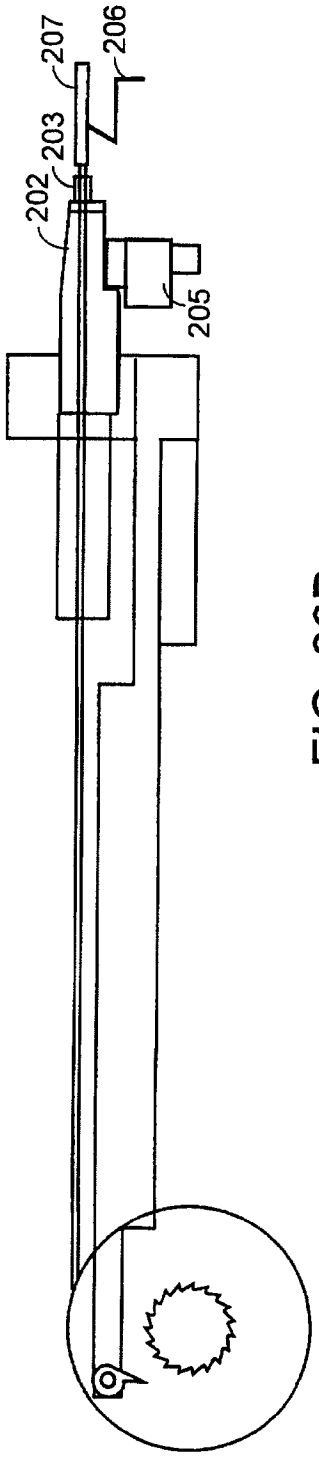

FIG. 26B

FIG. 27C

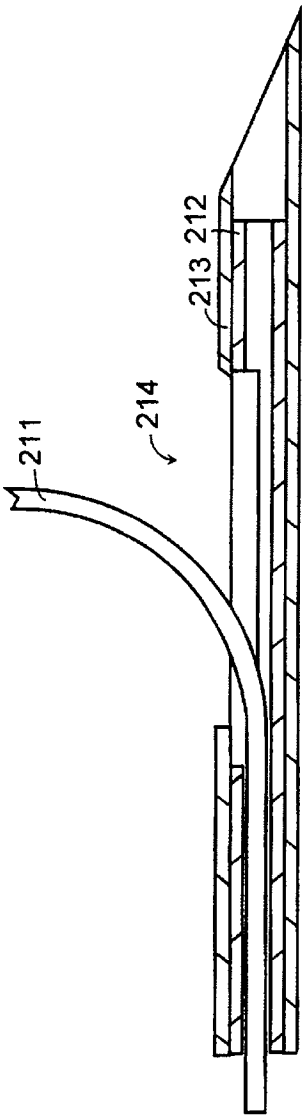

FIG. 27A

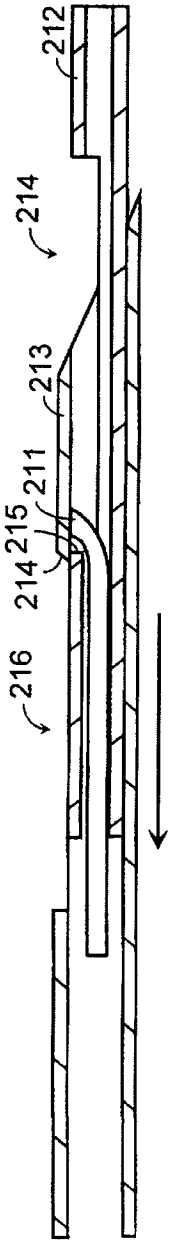

FIG. 27B

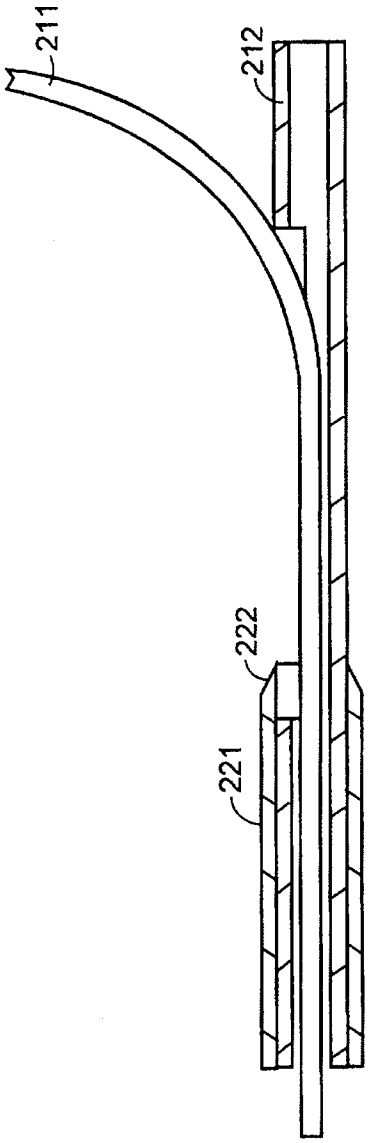

FIG. 28A

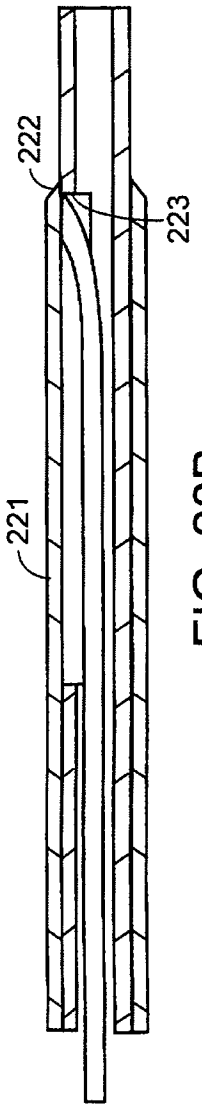

FIG. 28B

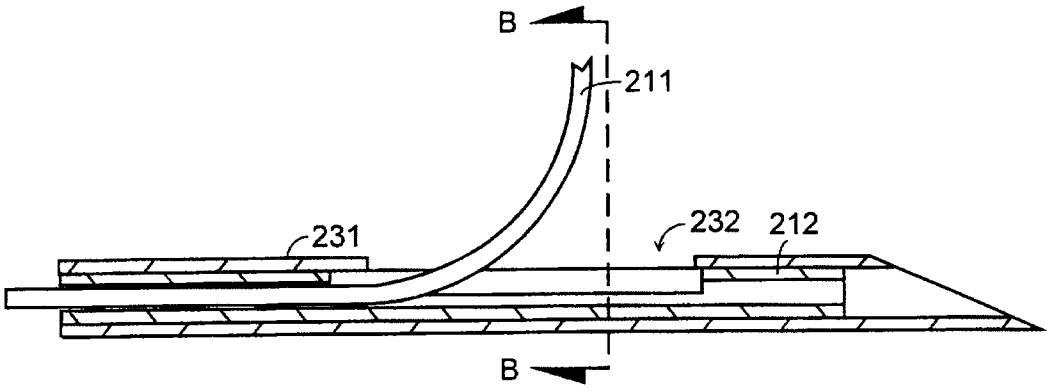

FIG. 29A

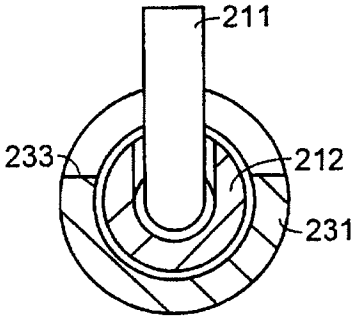

FIG. 29B

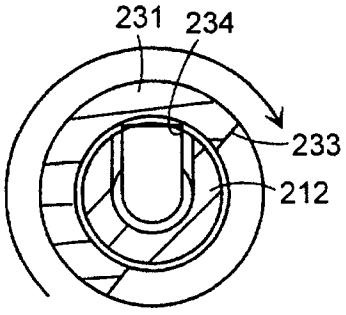

FIG. 29C

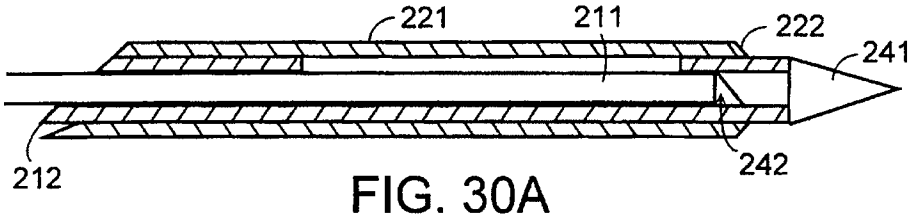

FIG. 30A

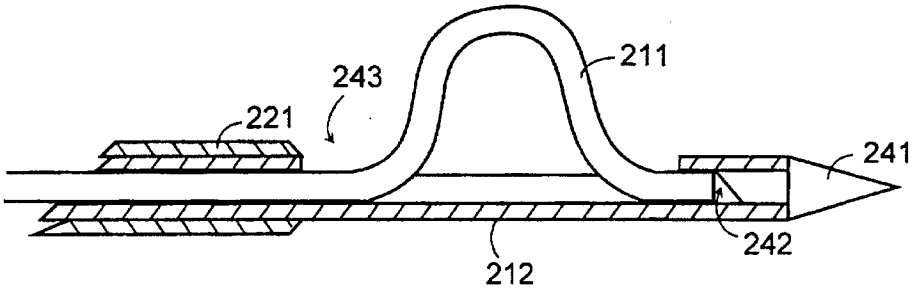

FIG. 30B

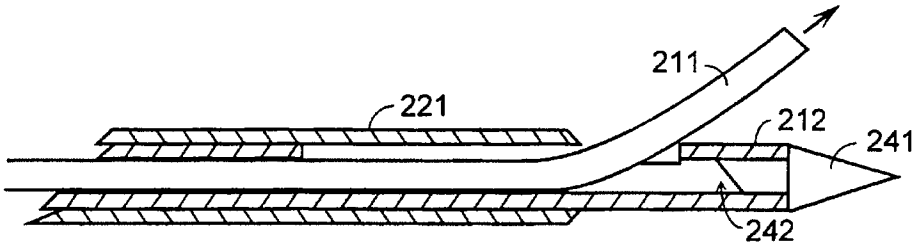

FIG. 30C

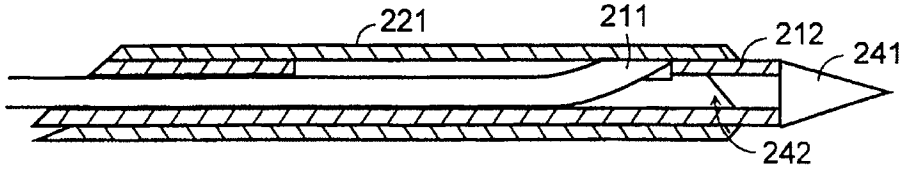

FIG. 30D

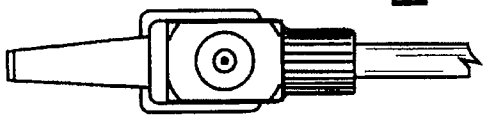

FIG. 31B

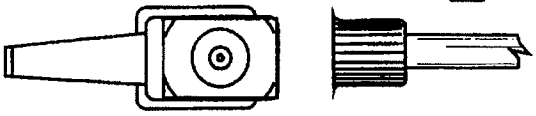

FIG. 32B

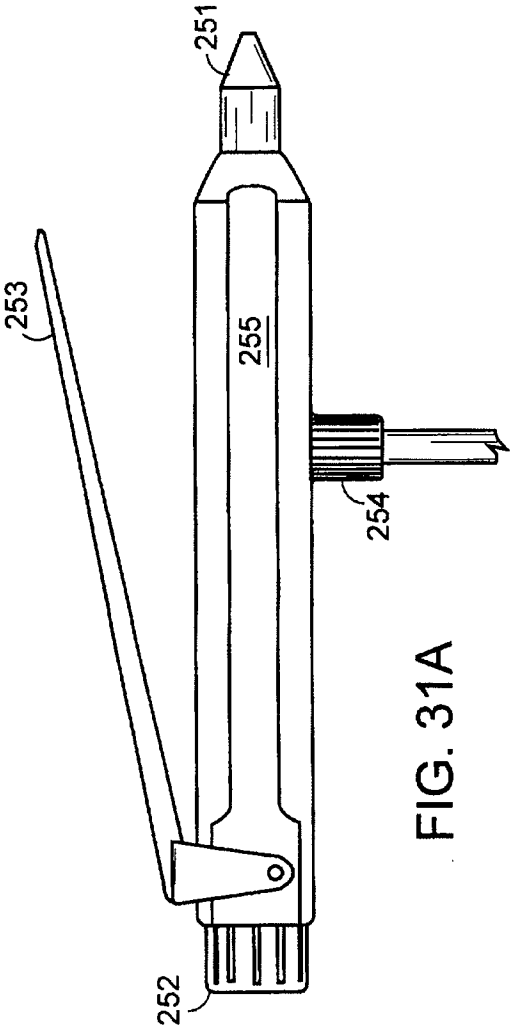

FIG. 31A

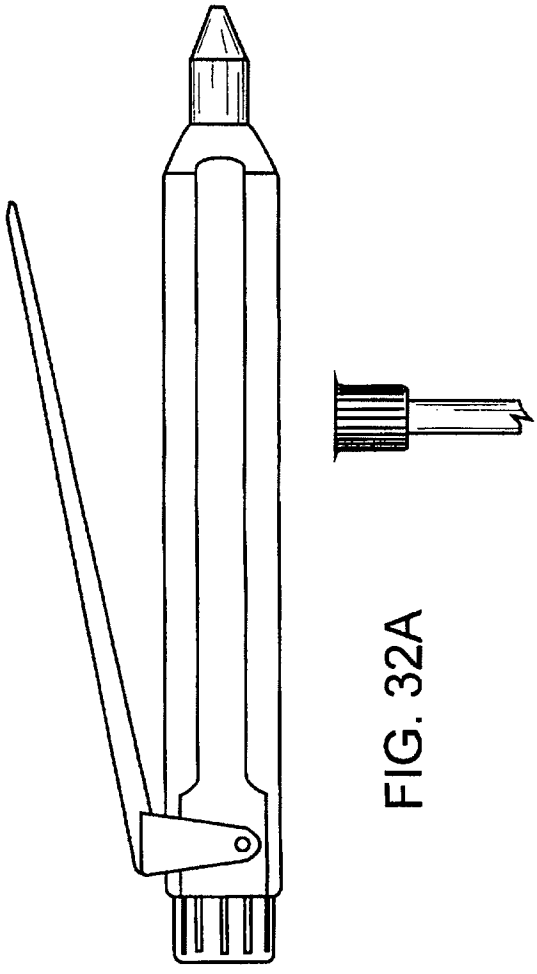

FIG. 32A